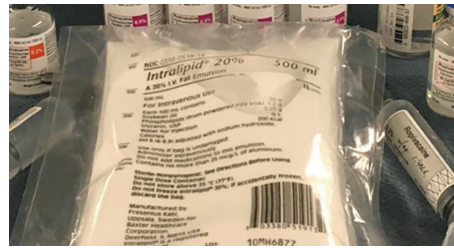


Local Anesthetic Systemic Toxicity (LAST) Revisited: A Paradigm in Evolution

by Guy Weinberg, MD; Barbara Rupnik, MD; Nitish Aggarwal, MD, MBA; Michael Fettiplace, MD, PhD; and Marina Gitman, MD

INTRODUCTION

Combined clinical and basic science efforts over several decades have enhanced our understanding of the underlying mechanisms and clinical spectrum of local anesthetic systemic toxicity (LAST). The *APSF Newsletter* has played an important role in educating clinicians and increasing awareness of the various presentations and optimal treatment of LAST, undoubtedly improving patient outcomes from this life-threatening iatrogenic complication. The changing landscape of regional anesthesia, characterized by new uses and forms of local anesthetics, has led to recent shifts in the clinical features and context of LAST.



In particular, the adoption of ultrasound guidance, catheter and intravenous infusions, local infiltration, and the expanding roles of regional anesthesia and local anesthetics in ERAS, multimodal analgesia, and possible cancer risk modification, require attention to the changing features of LAST.

INCIDENCE

LAST can happen in any practice setting, but it is often ignored or underappreciated by practitioners until experienced firsthand. Reported estimates of its frequency vary greatly. Although some single-site studies at academic institutions report extremely low rates of LAST,¹ recent analyses of large registry² and administrative^{3,4} databases generally agree on a rate of approximately 1 per 1000 peripheral nerve blocks. However, given the strong likelihood of under-reporting, misdiagnosis, or other causes of failed case capture, it is possible the actual rate is higher.

See “LAST Revisited,” Page 5

A Patient With E-Cigarette Vaping Associated Lung Injury (EVALI)—Coming to an Operating Room Near You!

by Todd Dodick, MD, and Steven Greenberg, MD

INTRODUCTION

The use of e-cigarettes, commonly referred to as vaping, has increased exponentially in the past several years. E-cigarettes were initially marketed as a smoking cessation aid, but their use among adolescents and young adults doubled from 2017 to 2019. In early 2019, cases of e-cigarette, or vaping, product use associated lung injury (EVALI) began to be presented to hospitals across the United States. Although other chemicals have been implicated in EVALI, The Centers for Disease Control and Prevention (CDC) has now suggested that vitamin E acetate, commonly added to illicit cannabis vaping liquids, is the most likely cause of EVALI.¹ As of December 10, 2019, a total of 2409 cases have been reported to the CDC.¹

THE CASE

Recently, in our institution, a 30-year-old male presented to our emergency department with shortness of breath, daytime sweats, chills, and progressive shortness of breath. He reported “vaping all day” and admitted to vaping both tetrahydrocannabinol (THC) and nicotine for the last 5 years. After a battery of tests were negative, severe EVALI was presumed, which required ICU admission with high FiO₂ and PEEP requirements. The patient was started on IV methylprednisolone 40 mg twice per day. During his ICU stay, he developed an acute left tension pneumothorax while on non-invasive ventilation requiring chest tube placement and endotracheal intubation. The patient was found to have bilateral apical blebs on chest computer tomography scan. After being weaned from the ventilator, our thoracic surgeons scheduled pleurodesis and resection of a large bleb due to a persistent large left pneumothorax despite persistent chest tube therapy.



In the operating room, he was appropriately preoxygenated, but rapidly desaturated to an SpO₂ of 51% following induction of anesthesia, recovering to SpO₂ >90% with manual ventilation. Oxygenation and ventilation during one-lung ventilation were expectedly difficult.

See “Vaping,” Page 4

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5. Invited conference reports summarize clinically relevant anesthesia patient safety topics based on the respective conference discussion. Please limit the word count to less than 1000.

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Address all general, contributor, and subscription correspondence to:

Stacey Maxwell, Administrator
 Anesthesia Patient Safety Foundation
 Charlton 1-145
 Mayo Clinic
 200 1st Street SW
 Rochester, MN 55905, U.S.A.
maxwell@apsf.org

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

Steven B. Greenberg, MD
 Editor-in-Chief, *APSF Newsletter*
greenberg@apsf.org
 Edward A. Bittner, MD, PhD
 Associate Editor, *APSF Newsletter*
bittner@apsf.org

Jennifer M. Banayan, MD
 Associate Editor, *APSF Newsletter*
banayan@apsf.org

Meghan Lane-Fall, MD
 Assistant Editor, *APSF Newsletter*
lanefall@apsf.org

Send contributions to:

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2020 President's Report: What APSF is Doing to Promote Perioperative Patient Safety and How Each of Us Can Make a Positive Impact

by Mark A. Warner, MD

There are many opportunities available to us as a specialty as well as individually to improve the safety of our patients as they go through their perioperative episodes of care. As a specialty, and for APSF, specifically, we must prioritize high-value issues that need to be addressed. As individuals, we must focus acutely on the safety of each and every one of our patients...every day.

APSF'S PATIENT SAFETY PRIORITIES AND PARTNERSHIPS

There are specific issues that we all know need to be addressed. Table 1 provides a list of the top perioperative patient safety issues that the APSF believes need targeted attention, discussion, and support at this time, no matter where you live and work. We use this set of global priority issues to help us determine the topics of our Stoelting Conferences, solicit articles for our *APSF Newsletter*, drive social media content, and allocate resources for research and education projects.

Beyond these global topics on perioperative patient safety, there are local issues that impact patient safety. Examples include limitations on personnel, equipment, and medications. While present to some degree everywhere, these limitations are most prevalent in lower resource countries. These issues often must be



Dr. Mark Warner, APSF President

addressed through global as well as regional or local partnerships. The APSF is partnering with the World Federation of Societies of Anaesthesiologists (WFSA) and other global and regional organizations to assist with improving education opportunities for anesthesia professionals. Specific to the WFSA, we are supporting efforts to ensure that the value of subspecialty fellowships offered by the WFSA around the world is

consistently high. We also are collaborating with the Patient Safety Movement Foundation to develop an anesthesia-specific patient safety curriculum for training programs and for individual practitioners, with adaptations that will make it applicable for use in both high- and limited-resource countries. Thanks to the efforts of our newsletter and social media leaders, Steven B. Greenberg, MD, and Marjorie P. Stiegler, MD, respectively, APSF's patient safety recommendations and articles now reach more than 600,000 anesthesia professionals worldwide, in every country and on every continent of the globe, with information on important topics in perioperative patient safety.

WHAT EACH OF US CAN DO TO HAVE A POSITIVE IMPACT ON PATIENT SAFETY

Beyond the efforts of APSF and many of our specialty's professional organizations to improve perioperative patient safety, there are actions we all can take to improve patient safety—individually and every day. For example, we can simply follow the Golden Rule, **"Treat others as you would like to be treated."** This rule is not tied to any culture and appears in some modification in all of the world's major religions and regions.

Basically, we need to take a few deep breaths before patients come under our care and consider how we would wish to be treated if we were in their places. Over the years I've had the good fortune to be able to study several major perioperative morbidities in detail (e.g., pulmonary aspiration, ulnar neuropathy, and pneumonias). I've also had the misfortune to have cared for patients who have suffered from these and other significant perioperative complications. Like many of you, I've seen patients receive medications in error, sometimes with significant detrimental events associated with them. I can tell you from personal experience that an unanticipated perioperative infection is not the outcome you wish to have. While many of these morbidities have complex, confounding etiologies that involve patient characteristics and patient care that spans the perioperative continuum, we can and must do better at reducing our personal errors or omissions that can negatively impact the safety of our patients. It is the right thing to do for our patients. It is what we would want from our colleagues when we are the patients.

Before providing care for individual patients, we might ask ourselves:

- Have we used checklists to ensure that we have everything we need at hand when we proceed with anesthetic care?

See "President's Report," Next Page

Table 1: APSF's 2020 Top Ten Perioperative Patient Safety Priorities

1. Preventing, detecting, and mitigating clinical deterioration in the perioperative period
 - a. Early warning systems in all perioperative patients
 - b. Monitoring for patient deterioration
 - i. Postoperative continuous monitoring on the hospital floor
 - ii. Opioid-induced ventilatory impairment and monitoring
 - iii. Early sepsis
 - c. Early recognition and response to decompensating patient
2. Safety in out-of-operating room locations such as endoscopy and interventional radiology suites
3. Culture of safety: the importance of teamwork and promoting collegial personnel interactions to support patient safety
4. Medication safety
 - a. Drug effects
 - b. Labeling issues
 - c. Shortages
 - d. Technology issues (e.g., barcoding, RFID)
 - e. Processes for avoiding and detecting errors
5. Perioperative delirium, cognitive dysfunction, and brain health
6. Hospital-acquired infections and environmental microbial contamination and transmission
7. Patient-related communication issues, handoffs, and transitions of care
8. Airway management difficulties, skills, and equipment
9. Anesthesia professionals and burnout
10. Distractions in procedural areas

Follow the Golden Rule: "Treat Others As You Would Like To Be Treated"

From "President's Report," Preceding Page

- Have we actively avoided contamination of our equipment and medications to reduce the risk of microorganism transmission perioperatively?
- Have we made the effort to know our patients and their risk factors for potential intraoperative or postoperative complications?
- Have we allowed production pressures or distractions (e.g., cell phones) to interfere with our focused efforts to provide the best care we can?
- Have we provided the appropriate handoff communication before leaving the patients in another anesthesia professional's care?
- **Are we "treating our patients as we would like to personally be treated"?**

For all of our patients, we might ask:

- Have we participated in our local institutions to develop the clinical pathways, practices, and policies that increase their safety throughout the perioperative period?
- Have we worked within our institutions and with our colleagues to improve team interactions and implement the cultural changes that allow all members of the perioperative team to point out actions that might cause patient harm?
- Have we taken leadership roles, locally or beyond, that allow us to make a positive impact on the perioperative safety of the populations we serve?

Perioperative patient safety is not something that someone else can resolve. The APSF and other organizations can provide the resources

to assist clinician investigators and others to develop new knowledge that can improve patient safety. These organizations can help develop recommendations that can be used to guide care and potentially improve patient safety. Our industry partners can develop the new equipment and medications that contribute to safer care. However, each of us has a personal responsibility to contribute to improved perioperative patient safety. Deliberate consideration of the Golden Rule before providing care to each patient seems essential.

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

Dr. Warner has no disclosures with regards to the content of the article.

Perioperative Management of EVALI Patients is Challenging

From "Vaping," Cover Page

Physiologic derangements included a PaCO₂ of 78 mmHg with an ETCO₂ of 47 mmHg, indicating significant dead space, and a PaO₂ of 69 mmHg on an FiO₂ of 1.0 indicating a significant A-a gradient. The PEEP was 8 cm H₂O and plateau pressure was 32 mmHg. The procedure was successful and he was returned to the ICU. Several days later, while he was no longer requiring positive pressure ventilation, he developed another tension pneumothorax in the contralateral lung. He again underwent pleurodesis and bleb resection.

DISCUSSION

To our knowledge, no case reports describe the intraoperative management of a patient with EVALI, with only one other EVALI-associated pneumothorax noted previously.^{2,3} Intraoperative ventilation of these patients may be challenging, and high levels of FiO₂ and PEEP may be required to maintain adequate gas exchange. If significant difficulty is expected, venovenous extracorporeal membrane oxygenation may be warranted in capable centers.

Patients with EVALI present almost universally with constitutional, respiratory, and gastrointestinal symptoms. Common presenting symptoms and findings are detailed in Table 1. Severity can range from mild, not requiring hospitalization (5–10%) to severe, requiring ICU admission (44–58%) and, often, non-invasive ventilation (32–36%) or intubation with mechanical ventilation (11–32%).²⁻⁴ Management of these patients is largely supportive, with lung protective ventilation with low tidal volumes and high PEEP employed similar to those used in Acute Respiratory Distress Syndrome. Empirical

Table 1: Suggested Diagnostic Criteria for EVALI^{3,4}

Use of e-cigarettes
Pulmonary infiltrate on chest radiograph or ground glass opacities on computerized tomography (CT) scan
Elevated WBC count and inflammatory markers (c-reactive protein, erythrocyte sedimentation rate)
Absence of pulmonary infection—negative for respiratory viruses including influenza, negative HIV or HIV-related infections, negative blood, sputum and/or bronchial alveolar lavage (BAL) cultures
Foamy macrophages containing vitamin E acetate on BAL/lung pathology ⁴
No evidence of alternative medical causes (e.g., heart failure, rheumatologic disease, cancer)

corticosteroids may be beneficial, and have been widely administered in published reports.⁴ Thus far, the CDC has documented 52 deaths across the United States.¹ While much remains to be elucidated regarding EVALI, e-cigarette use is increasingly prevalent. We are likely to see more cases in our hospitals and increasingly, our operating rooms in the future.

Dr. Dodick is an anesthesiologist in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem, Evanston, IL, and is clinical instructor in the Department of Anesthesia and Critical Care at the University of Chicago Pritzker School of Medicine, Chicago, IL.

Dr. Dodick has no conflicts of interest.

Dr. Greenberg is vice chair of Education in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem, Evanston, IL, and is clinical professor in

the Department of Anesthesia and Critical Care at the University of Chicago Pritzker School of Medicine, Chicago, IL.

Dr. Greenberg is editor-in-chief of the APSF Newsletter.

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Risk Factors For LAST

From “LAST Revisited,” Cover Page

Notably, Morwald et al. identified an overall rate for signs and symptoms consistent with LAST of 1.8/1000 peripheral nerve blocks during joint replacement; however, for the use of lipid emulsion, considered a surrogate for LAST, in the same population, they identified, for 2014, a rate during knee replacement of 2.6/1000 or 1 in 384 surgeries with a block.³ For a “rare event,” that’s not so rare! This reminds us of the need to remain vigilant for the possibility of LAST in virtually any patient receiving local anesthetic.

RISK

Understanding factors that increase risk is vital, as identifying patients with an elevated susceptibility to LAST enables clinicians to modify treatment and reduce the risk. Hypoxia and acidosis were recognized decades ago as factors predisposing to LAST.⁵ More recently identified co-morbidities include pre-existing heart disease (especially ischemia, arrhythmias, conduction abnormalities, and low ejection fraction), extremes of age, frailty, and conditions that cause mitochondrial dysfunction (e.g., carnitine deficiency); liver or kidney disease can also increase the risk of delayed LAST by depressing local anesthetic metabolism or disposition.⁵ Interestingly, Barrington and Kruger² examined a registry of ~25,000 peripheral nerve blocks performed in Australia from January 2007 to May 2012 and identified 22 cases of LAST (overall incidence, 0.87 per 1000). They found that ultrasound guidance lowered the risk of LAST (odds ratio, 0.23, CI: 0.088–0.59, $p=0.002$)—presumably a result of fewer unidentified intravascular injections and possibly lower volumes of the drug used to achieve a block. Nevertheless, no single method can completely eliminate these events and roughly 16% of reported LAST occurred despite the use of ultrasound. Barrington and Kruger also noted that small patient size was a risk factor for LAST. The role of skeletal muscle as a large reservoir compartment for local anesthetic may explain this phenomenon and was confirmed in a rat model by Fettiplace et al.⁶ It is reasonable to adjust local anesthetic dose in all such “at-risk” patients or possibly avoid peripheral nerve block or local anesthetic infusion entirely if the risk is deemed too consequential. Surprisingly, Barrington and Kruger found 16 cases involving ropivacaine and the remainder were lidocaine-induced; notably, the LAST rate with lidocaine was approximately 5 times greater than that for ropivacaine.

SETTING

Three large-scale studies have reviewed published case reports to identify the clinical spectrum of LAST over the past 40 years: DiGregorio et al.⁷ (Oct 1979–Oct 2009); Vasques et al.⁸ (March 2010–March 2014); and Gitman and Barrington⁹ (January 2014–Novem-

Table 1: Management of LAST

CLINICAL FEATURES OF LOCAL ANESTHETIC TOXICITY

Risk Factors	Prevention
<ul style="list-style-type: none"> • Hypoxia or acidosis • Extremes of age • Small patient size or muscle mass • Frailty • Heart disease: <ul style="list-style-type: none"> – Coronary artery disease, low cardiac output, arrhythmias, bundle branch blocks • Mitochondrial dysfunction • Liver or kidney disease • Carnitine deficiency 	<ul style="list-style-type: none"> • Use of lowest effective dose • Use of vascular marker (e.g., epi) • Adequate monitoring • Incremental injection • Intermittent aspiration • Individualized dosing • System safety (e.g., preparedness) • Educating doctors and nurses • Assessing patient risk factors

Presenting Symptoms and Signs

Prodrome	Major CNS	Major CV
<ul style="list-style-type: none"> • Tinnitus • Metallic taste • Hypertension • Tachycardia 	<ul style="list-style-type: none"> • Agitation/confusion • Obtundation • Seizure • Coma 	<ul style="list-style-type: none"> • Bradycardia/heart block • Hypotension • Ventricular tachycardia or fibrillation • Asystole

Treatment of Local Anesthetic Systemic Toxicity

1. Stop administering local anesthetic/call for help
2. Manage airway
3. Control seizures with benzodiazepine
4. CPR as needed
5. 20% lipid emulsion 1.5 mL/kg (bolus given over 2–3 min)

Initial resuscitation of LAST differs from standard CPR by focusing on reversing underlying toxicity rather than or in addition to sustaining coronary perfusion. Hence, initial emphasis is on seizure suppression and establishing normal arterial oxygen saturation since both acidosis and hypoxia aggravate LAST. For severe LAST, contact a perfusion team early to assure a path to extracorporeal support should CPR fail. During CPR, avoid local anesthetic anti-arrhythmics (they worsen LAST), beta blockers and calcium channel blockers (they depress contractility), and vasopressin (increasing afterload alone is undesirable since the poisoned heart doesn’t contract well). Epinephrine is acceptable for treating hypotension but should be used in small doses since it can impair lipid resuscitation, e.g., boluses <1 mcg/kg. Following the initial bolus of lipid emulsion given over 2–3 minutes, persistent LAST can be managed with repeated boluses and/or infusing lipid (0.25 mL/kg/min until stable or 200–250 mL/15–20 min). MAX DOSE: 12 mL/kg, ideal body weight. Propofol is not a substitute for lipid emulsion.

ber 2016). Data from these papers paints a picture of the evolving context of LAST with the latter two specifically covering the past decade. Between 1979 and 2009, epidural anesthesia and brachial plexus block each comprised around one-third of LAST cases. However, over the last decade, neuraxial (epidural and caudal) anesthesia has contributed only about 15% of published cases of LAST. Extremity blocks now make up about 20% of cases, and there are signals of concern related to both the penile block and local infiltration, each accounting for roughly 20% of reported cases. Interestingly, one institution reported a spike in LAST associated with

dorsal penile block.¹⁰ They adopted system improvements in administering local anesthesia that led to an abrupt cessation of these events. The reviews indicate LAST has also been described after continuous intravenous infusion; paravertebral, peribulbar, transabdominis plane, and maxillary nerve blocks; topical administration in gel form; and after oral, esophageal, or tracheal mucosal application. A recent report described cardiac arrest after submucosal nasal injection of 120 mg of lidocaine.¹¹ Clearly, LAST can occur anytime local anesthetics are used.

See “LAST Revisited,” Next Page

LAST Can Have Delay in Onset

From “LAST Revisited,” Preceding Page

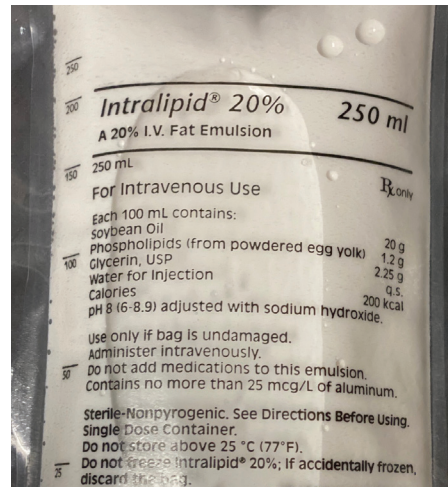
Roughly 80% of LAST cases over the past decade occurred in hospitals, ~10% in offices, and the remainder in emergency rooms or even at home. Anesthesia professionals or trainees were involved in about 60% of cases, with surgeons involved in approximately 30%, and the remainder spread among dentists, emergency physicians, pediatricians, cardiologists, and dermatologists. This reminds us of the need to take every opportunity to educate our colleagues about the risks and management of LAST.

TIMING

The three large-scale studies show a trend to progressive delay in the onset of LAST over the past 40 years, reflecting the advent of both ultrasound guidance and catheter-based techniques. Competent use of ultrasound can reduce the chance of intravascular injection and immediate-onset LAST. Delays of more than 10 minutes in single-shot blocks occurred in only ~12% of cases before 2009 but in ~40% of those published in the last decade. Recent reports describe LAST with an onset that is temporally removed from the start of treatment by several hours or even days for catheter or intravenous infusion. This presumably occurs as the result of drug accumulation in target tissues and is a particular concern since both the timing and setting are problematic. The long interval can obscure the connection to local anesthetic administration; moreover, when LAST occurs “off-site,” away from the operating rooms, where it is rarely seen, the responsible caregivers are probably less mindful or knowledgeable of the problem, its detection, and treatment.

PRESENTATION

LAST provokes a variable array of signs and symptoms of central nervous system (CNS) and cardiovascular (CV) toxicity (Table 1). These can be mild or severe and can occur separately or together. Isolated CNS symptoms occur in approximately half of reported cases, combined CNS and CV symptoms in about one-third and isolated CV symptoms in the remainder. Many of the latter occurred under general anesthesia or heavy sedation where CNS toxicity is difficult to ascertain. Seizure was the most common initial sign overall, occurring in roughly 50% of cases. Minor CNS features or “prodromes” such as tinnitus, metallic taste, hallucinations, slurred speech, limb twitching, extremity paresthesia, intention tremor, facial sensorimotor, and eye movement abnormalities were noted in only about 16% of patients by DiGregorio et al., but about 30% in combined data from Vasques et al. and Gitman et al.; this is consistent with an



increase in LAST secondary to absorption or gradual onset during infusion. The most common presenting features of CV toxicity were arrhythmias (including bradycardia, tachycardia, VT/VF), conduction disturbances (bundle branch block, AV conduction block, widened QRS), hypotension, and cardiac arrest (including nonshockable rhythms, PEA, and asystole). Progressive toxicity (especially hypotension and bradycardia) with rapid deterioration over minutes is typical of severe LAST. It is impossible to predict which patients will progress. However, early treatment can delay or prevent progression; therefore, it is important to be prepared to intervene early in any patient receiving local anesthetic who has signs or symptoms consistent with LAST.

LIPOSOMAL FORMULATION

Liposomal bupivacaine (LB) harbors local anesthetic in a nanoparticle carrier matrix designed to prolong its action by slow release. Exparel® (Pacira Pharmaceuticals, San Diego, CA) comes in a 20-mL vial containing a total of 266 mg (1.3%) bupivacaine, which is the manufacturer’s maximum recommended dose for an adult patient. It was approved by the Food and Drug Administration (FDA) in 2011 for injection directly into the operative site to augment post-operative analgesia and later in 2018 for interscalene brachial plexus block.¹² Three percent of the drug is free and presumably initiates a certain level of analgesia upon administration. Blood levels of bupivacaine can last up to 96 hours after injection of LB; therefore, patients must be adequately monitored for delayed toxicity. As with any local anesthetic, patients with specific co-morbidities are at an increased risk for developing acute or delayed toxicity, either as a result of increased sensitivity (e.g., ischemic heart disease) or impaired metabolism (e.g., liver disease) with resulting increased plasma levels of bupivacaine.

Administration of non-bupivacaine local anesthetics within 20 minutes of Exparel, which can occur when a surgeon and an anesthesia professional fail to communicate, may cause a sudden release of liposomal bupivacaine, dangerously increasing free plasma bupivacaine concentrations; the exact mechanism of this phenomenon is not elucidated. Toxicity of the two local anesthetics is then additive. Burbridge and Jaffe¹³ emphasize the importance of safety measures such as educating the operating room staff as well as a “time-out” label on the drug vial to prompt discussion around avoiding simultaneous administration of other local anesthetics within 20 minutes of Exparel injection.

The FDA Adverse Event Reporting System (FAERS) database contains reports submitted by practitioners and consumers. An analysis of FAERS data received between January 1, 2012, and March 31, 2019, where Exparel was listed as the suspect medicinal product and signs or symptoms of LAST occurred (seizure or both CNS symptoms and CV disturbance), were studied by disproportionality analysis—a pharmacovigilance tool that measures the “Information Component” (IC025) and is used by the World Health Organization.¹⁴ This compares the rate at which a particular event of interest co-occurs with a given drug versus the rate this event occurs without the drug in the event database. If the lower limit of the 95% confidence interval of the IC025 is greater than zero, then there is a statistically significant signal. Such an adverse event signal was found between LAST and liposomal bupivacaine. From January 1, 2012, to March 31, 2019, the analysis yielded an overall IC025 of 1.65. Splitting the dataset into two time periods (January 2012 to December 2015 and January 2016 to March 2019) showed persistence of a significant signal in both time periods. While this does not prove a causal relationship, it nevertheless points to a statistically significant signal between Exparel and signs or symptoms of LAST.

REPORTING OF LAST IS PROBLEMATIC

A recent Cochrane Library update of perioperative intravenous lidocaine infusion by Weibel et al.¹⁵ found that of 68 clinical trials comparing lidocaine infusion with thoracic epidural analgesia, 18 did not comment on adverse events at all. Unfortunately, the degree of heterogeneity in the reporting methods of the remaining 50 studies precluded a meta-analysis of these data. There is clearly a need to improve and standardize ascertainment and reporting of LAST in clinical trials involving local anesthetics. This applies particularly to studies of catheter and intravenous infusions where systems for identifying LAST are not as robust as in the operating room. Until this

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Treating LAST Involves Administering Large Quantities of Lipid Emulsion Quickly

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occurs, understanding the associated risks will remain hampered by reliance on anecdotal reports and personal experience.

TREATMENT

In 2010 the Association of Anaesthetists of Great Britain and Ireland (AAGBI) and the American Society of Regional and Pain Medicine (ASRA) Working Group on Local Anesthetic Toxicity separately published first-ever recommendations for a systematic approach to treating LAST.¹⁶ Both groups focused on airway management and seizure suppression along with the rapid infusion of lipid emulsion as key elements specific to treating LAST (Table 1). Interestingly, the rate of published reports increased from ~3 LAST cases per year before 2009 to ~16/year in the last decade. If reporting bias is constant, this could reflect greater willingness to report events as patient outcomes improved over the past decade. ASRA has updated their advisory twice since 2010 with modifications that include the adoption of a checklist approach and a simpler method for infusing lipid emulsion.⁵ Two key points deserve mention. First, mechanism informs method. Infusing lipid emulsion reverses LAST by accelerating the redistribution of local anesthetic.⁶ This results from partitioning and a direct inotropic effect exerted by lipid emulsion¹⁷ that combine to “shuttle” drug away from sensitive organs (brain, heart) to reservoir organs (skeletal muscle, liver). This requires infusing a relatively large quantity of lipid quickly (e.g., ~1.5 mL/kg over ~2 minutes) to establish a lipid “bulk phase” in the plasma. The bolus infusion may be repeated or followed by an infusion at a slower rate—the difference in method is likely not as important as the need to sustain a bulk phase. An important study by Liu et al.¹⁸ showed in a rat model of bupivacaine toxicity that repeated bolus dosing is superior to bolus + infusion in reversing LAST. However one chooses to deliver lipid, it is important to respect the upper dosing limit of ~10–12 mL/kg ideal body weight to avoid fat overload. That is, don’t forget to turn it off! Second, the treatment strategy for CV instability in LAST differs from that used for ischemic cardiac arrest since the underlying pathophysiology of ischemia and pharmacotoxicity differ. Therefore, it is preferable to treat the underlying toxicity by infusing lipid and, if needed, use reduced doses of epinephrine (boluses ~1 mcg/kg) to support blood pressure.¹⁹ Vasopressin should be avoided since increasing afterload alone has no benefit and a deleterious effect has been confirmed in animal models.²⁰ It is sensible to alert a

perfusion team at the outset of a severe event so that alternative, extracorporeal methods of circulatory support can be readied should initial resuscitation fail.

CONCLUSIONS

LAST can occur anytime local anesthetics are used. Even with appropriate dosing and perfect technique, patient susceptibility, system problems, and random errors prevent its eradication. The increasing use of regional anesthesia in an aging population, and the advent of catheter and intravenous infusion of local anesthetic for opiate-sparing anesthesia, multimodal analgesia, or cancer risk modification assure that LAST will continue to occur increasingly at unexpected sites and with delayed timing despite our best efforts. Identifying “at-risk” patients and improving system safety will reduce the likelihood of LAST.

Clinicians should have a treatment plan ready for LAST wherever local anesthetics are used. Any unusual CNS signs or CV instability in the setting of regional anesthesia, anesthetic infiltration, or infusion should be considered possible LAST until proven otherwise, since early intervention can prevent or slow progression. Anesthesia professionals must actively educate other health care providers who administer local anesthetics to patients. This includes informing those in other specialties having a syringe in hand and staff on the floor responsible for care of patients receiving local anesthetic infusion. Improved models of LAST and its treatment will continue to inform measures we can adopt to improve patient safety and save lives.

Dr. Weinberg is a professor of Anesthesiology at the University of Illinois College of Medicine at Chicago and staff physician at the Jesse Brown VA Medical Center, Chicago, IL.

Dr. Rupnik is a consultant anesthetist at the Balgrist University Hospital, Zurich, Switzerland.

Dr. Aggarwal is a hospital resident at Yale New Haven hospital, New Haven, Connecticut.

Dr. Fettiplace is a resident in Anesthesiology at Massachusetts General Hospital, Boston, MA.

Dr. Gitman is an assistant professor of Anesthesiology at the University of Illinois College of Medicine, Chicago, IL.

Dr. Weinberg is an officer and shareholder of ResQ Pharma, Inc., and maintains the educational website, www.lipidrescue.org. Drs. Rupnik, Aggarwal, Fettiplace, and Gitman have no conflicts of interest.

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Healthy Relationships Between Anesthesia Professionals and Surgeons Are Vital to Patient Safety

by Jeffrey B. Cooper, PhD

Effective teamwork in perioperative teams is a prerequisite for patient safety. Yet, what is rarely discussed openly is the special importance of dyads in teams—the relationship between two individuals. If you're an anesthesia professional, you likely are aware, at least subliminally, of the erosion of patient safety when you are working with a surgical colleague with whom your relationship is not a pleasant one. At the least, it can make for an unpleasant workday experience; at worst, a dysfunctional relationship can be a critical element that enables or causes an adverse outcome. On the flip side, when one is working with a trusted, respected colleague and the feeling is mutual, you are much more likely to have a happy day and your patient is more likely to have an optimal outcome.^{1*} I addressed this topic in a commentary published simultaneously in *Anesthesiology* and *The Journal of the American College of Surgeons* (an unusual occurrence) and more recently, in my presentation for the annual Ellison C. Pierce, Jr., MD, Lecture hosted by the APSF and the ASA.^{2,3} I summarize here key observations and suggestions for action.

In the presentation and the article, I focus on the dyad between the physicians in the team, anesthesiologists and surgeons. I do note that the other dyads are also of high importance to patient safety, i.e., that between surgeon and OR nurse and between surgeon and any anesthesia professional. Yet, my gut tells me that there are aspects of the physician dyad that create the potential for particularly problematic dysfunction; that is my current focus (maybe I'll get to the others soon). Why did I choose to focus attention on this topic? Over the years (47 plus since I began working in health care), in various quarters, I'd heard one too many anecdotes about adverse events that were either caused by relationship dysfunction or could



have been prevented by a positive relationship. More importantly, I'd heard one too many disrespectful remarks that represented stereotypes that anesthesia professionals have about surgeons. I don't have as much opportunity to hear similar comments from surgeons, but when I've probed, I have found similar stereotypes there as well. While the stereotypes and disrespectful remarks are not in themselves potentially harmful to patients, the attitudes they represent can lead to communication failures and lack of collaboration and collegiality that can either cause, enable, or fail to prevent an adverse event.

Some of the specific negative stereotypes are listed in Table 1. These come from years of listening as well as my seeking input from surgeon and anesthesiologist colleagues, near and far, with both private practice and academic experiences. Again, I have no data on which to provide concrete evidence, but no one I've presented this to has challenged any of the comments nor pushed back on my assertion that this is too prevalent and not healthy.

Considering how important it is that surgeons and anesthesiologists work collaboratively, it is surprising that there is little research about this topic, almost none specifically about the anesthesiologist-surgeon dyad. Lorelei Lingard and colleagues have, in several studies, examined situations where the discourse within the perioperative team revolves around conflict.⁴ One comment arising from those studies is that "Subjects' constructions of other professions' roles, values, and motivations were often dissonant with those professions' constructions of themselves." Related to that comment is the observation that "Team members use assumptions about speaker motivation to interpret communicative exchanges."

Jonathan Katz has specifically addressed conflict in the OR.⁵ He notes that "cancellation... for additional evaluation... is among the most frequent causes of conflict between surgeon and anesthesiologist." He also notes that sources of conflict present an opportunity for collaboration. A goal should be to turn all such opportunities into productive collaboration in the interest of the patient, seeking to learn what is right, not who is right.

Diana McLain Smith writes about how functional and dysfunctional dyads in leadership teams are critical to either success or failure in organizations.⁶ The characteristics and outcomes she describes are clearly applicable to perioperative care and to the leadership team in the OR. What is different about this construct from the usual discussion about teams is that the focus is on relationships between two individuals rather than on the team as a whole.

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*If you want to organize a focus group or presentation, I can send you a link to the animations I used during the lecture, including a shortened version of "There is a Fracture." (You can find the original on Youtube.) The other two animations are of the view surgeons have of anesthesiologists and of what a healthy collaboration would look like." (No charge. You just have to promise to use them for good.)

Table 1: Negative stereotyping

Examples of anesthesia professionals' stereotypes of surgeons:

- They never admit how much blood they've lost.
- They just want to make a lot of money doing more cases.
- They don't know anything about medical issues.
- They always underestimate how long the case will be.

Examples of surgeons' stereotypes of anesthesia professionals:

- They just want to go home early—don't care about my patient.
- They are ready to cancel a case at the drop of a hat.
- They're often distracted, not paying attention.
- They never tell us about the pressors they're using.

Building Healthy Perioperative Relationships

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Both are important. What I'm suggesting is that relationships between individuals are equally, if not more important, to understand and improve.

What are specific ways that the interactions in this dyad impact patient safety for better or worse? I've heard many stories in my almost 35 year's experience as a member of a quality assurance review committee and via many vignettes told to me as I've probed more into this topic. Consider an anesthesiologist, who even though junior, may be more expert than the surgeon in physiology, and who tried to communicate to the surgeons that their diagnosis did not comport with the data. Not having an established, trusting relationship with the surgeon, the surgeon disregarded his suggestions. When the anesthesiologist was right, the patient outcome was much worse than it might have been if the surgeon collaborated with him. Or the anesthesiologist who, despite the surgeon's extensive experience in performing cricothyrotomy, disregarded the surgeon's suggestion that it was time to move the difficult-airway algorithm along and the situation dangerously went downhill. These were true stories that are likely familiar to you.

There is the flip side: I heard independently from an anesthesiologist and surgeon about a situation where their prior trusting relationship was clearly an enabler for success. A needle with a pop-off suture had separated prematurely. The surgeons, unable to locate the needle, were fixated deep in the wound seeking to find it. The anesthesiologist, watching the struggle, waited for an appropriate moment to suggest a brief regrouping and consideration of options. That led to the use of fluoroscopy to find the needle. I've heard of situations as well where a surgeon gave his or her anesthesia colleague a heads-up the day before, or earlier, about a patient issue with anesthesia-related implications that averted a patient safety issue. I suspect that most anesthesiologists reading this have had similar experiences. Indeed, some of you are fortunate enough to have regular experiences of this latter type rather than the former. Every patient should be so lucky.

If what I'm describing rings true for you, what can be done to make this dyad function more routinely effective? I'm not aware of empirical evidence to guide suggestions, but there are some general principles about relationship-building that can apply. I've suggested in the article a few things that are

practical; yet, taking the first step isn't easy. In most relationships needing improvement, each party needs to “buy in.” You might think, “it's not mostly my fault; it's the surgeons who need to behave better.” I'm not judging who is more at fault when things aren't going well. But I can say for sure that nothing will get better if at least one person doesn't try to start a constructive dialogue.

Here's some suggestions, any one of which you could consider trying (I didn't make these all up. Many of your colleagues already do some of these. You can think of your own too):

- 1. Take a surgeon to lunch** or dinner. (this is an especially productive thing to do when a new surgeon joins your hospital)
- 2. Form a focus group** to discuss one of the articles in the references. Listen more than you talk. Seek to understand why behaviors you observe may come from different sources than you imagine.*
- 3. Work together on common issues**, e.g., lowering the risk of surgical infection, which anesthesia professionals might contribute to; implement emergency manuals together.
- 4. Assume the best intentions**, as in the “basic assumption”⁷ now widely taught in simulation and modified for this application as: “my surgical colleagues are intelligent, doing things in the best interest of their patients, and trying to improve.” It's not always so, but it mostly is.
- 5. When someone does something that makes you think “WTF;”** the “F” should stand for “frame.”⁸ Instead of attributing a negative stereotype, be curious, seek to find out what the rationale behind the action is. You are likely to learn something new; even if what the person is doing isn't optimal or right, it's usually for a good reason. If there's not a good reason, you'll have an easier time getting them to see things differently versus just assuming they are irrational.
- 6. Train together** in simulation with the entire team. It's a proven way to improve the team's crisis management skills. In addition, it puts you in a position to have dialogue at an equal level. More simulation programs are doing this. You could even take the lead and suggest a team try it out. Sure, it costs money and takes a lot to organize (just getting the people there is tough), but it'll pay off in lots of ways.
- 7. Read a book** about communicating across

relationships, e.g., “Difficult Conversations,”⁹ or “Thanks for the Feedback.”¹⁰ Relationships are hard. There's a lot to learn. Fortunately, there are lots of good models to learn from.

I'm not promising you a rosy world if you work at this. But I think it's worth your time for your patients' safety to try as much as you can. Doing nothing will mean nothing will change. If your efforts succeed, you'll have made a huge advance for patient safety, and you're likely to find more joy and meaning in your professional daily life.

Dr. Cooper is professor of Anaesthesia, Harvard Medical School and the Department of Anaesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital. He is a founder of the APSF, retiring from the Board of Directors and Executive Committee in 2018 after 32 years of service. This article is a summary of a portion of his lecture for the Ellison C. Pierce, Jr., MD, Memorial Lecture at the American Society of Anesthesiologists Annual Meeting, October 19, 2019.

Dr. Cooper reports no conflicts of interest.

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RAPID Response

to questions from readers

Airway Emergencies and Safety in Magnetic Resonance Imaging (MRI) Suite

by Heather McClung MD, and Rajeev Subramanyam MBBS, MD, MS, FASA

Dear Rapid Response,

Are MRI-compatible laryngoscopes recommended or required in the MRI environment?

I am an anesthesiologist presently working in a community hospital and care for patients who receive anesthesia as part of their MRI exam. We have conventional laryngoscopes and blades available in MRI zone III and an MRI-compatible anesthesia machine in zone IV. If we need to intubate a patient, the expectation is that we can move the patient to zone III for intubation and return to zone IV to complete the study. I believe we should purchase MRI-conditional laryngoscopes and blades to be available in zone III, but am told it is not essential and many other institutions do not have MRI-compatible laryngoscopes.

Please let me know your thoughts on this patient safety question.

Regards,
Dheeraj Nagpal, MD

Dr. Nagpal is an attending anesthesiologist at New York Presbyterian Queens, Flushing, NY.

Dr. Nagpal has no conflicts of interest.

Reply:

This is an important question to address since modern anesthesia practice must meet the present and growing demand to provide anesthesia care to adults and children who require MRI.¹ Further, the American Society of Anesthesiologists (ASA) closed claims project evaluated the risk and safety of anesthesia in remote locations and found that claims for death and specifically respiratory damaging events were more common in remote locations, most often during monitored anesthesia care. In addition, the majority of radiology claims were in MRI (7/10) and four of those claims were related to oversedation.² Given the unique patient safety concerns in the MRI environment, we believe laryngoscopes that are safe to use in the MRI environment should be available whenever anesthesia care

is being provided. Further, the process for airway rescue during emergencies in the MRI scanner needs to be clearly defined.

Providing safe care in the MRI arena requires a thorough understanding of the environment and potential hazards to patients and staff. The MRI environment is conceptually divided into four Zones designated I through IV. Zone III is typically reserved for MRI personnel and public access is restricted. The control room is in Zone III. Zone IV is the MRI scanner magnet room.³ The MRI magnetic field is invisible, always on, and can affect ferromagnetic equipment of any size in Zone IV, potentially converting it to a projectile that is drawn into the scanner with a strength and speed that can be deadly. Not only can patients be injured or killed, but damage to the scanner results in temporary closure and servicing or a costly and dangerous magnet quench. The unique safety concern of the magnetic field has significant impact on the care of patients presenting for anesthesia in MRI, and can become particularly challenging during an airway or medical emergency.

Very few airway devices have been specifically designed for safe use in MRI. Medical devices and equipment that might be used in the MR environments should be labelled as MR unsafe, MR conditional, or MR safe (Figure 1). Laryngeal mask airways and endotracheal tubes contain small amounts of ferromagnetic material in the pilot balloon, but are considered MR conditional as they will not cause patient harm but may affect image quality. These airway devices have been used safely along with plastic oropharyngeal airways and bag mask ventilation units. Classic metal laryngoscopes are considered unsafe as malfunction with sudden failure to operate can occur in Zone IV and nickel in the laryngoscope battery is ferromagnetic.⁴ Although expensive, single-use and reusable MRI-conditional devices are available.⁵ The quality of disposable laryngoscopes is variable but there are products available which are MRI-conditional and can be trialed to confirm that they are clinically acceptable. Whether single-use or reusable, MRI-conditional laryngoscopes can be brought into Zone IV safely.

The most recent ASA Practice Advisory on anesthesia care in MRI provides useful guidance for preparing to manage airway emergencies in MRI.⁴ During an airway emergency, anesthesia professionals and other health care providers must be prepared to enter Zone IV quickly. Though not listing specific devices, the advisory states that "Alternative MRI safe/conditional airway devices should be immediately available in the MRI suite."⁴ Given the sense of urgency, personnel must recheck themselves for presence of ferromagnetic objects and equipment prior to entering the scanner. To avoid confusion and the risks of MR-unsafe devices inadvertently getting into Zone IV, airway equipment immediately available to the team in Zone III should be MR-conditional for all scanners in the location. If it is safe, the airway should be supported with bag mask ventilation while the patient is removed from Zone IV to a nearby location in Zone III or Zone II where a full complement of airway and resuscitation equipment can be used and emergency personnel summoned for help. If securing the airway is deemed emergent in the scanner (e.g., profound vomiting with risk of aspiration, inability to ventilate, etc.), it can be done only if MR-safe and -conditional equipment is available. If MR-safe and -conditional equipment is not available, the patient must be moved out of Zone IV risking the complications of hypoxia. In any situation, medical emergencies are difficult to manage in Zone IV, and the patient should be brought out of Zone IV as soon as feasible. Until the patient is safe or removed from Zone IV, at least one person should be designated to police the heightened traffic entering Zone IV during an emergency. On some newer MRI machines, the MRI table can be undocked from the magnet to move the patient from Zone IV and minimize the loss of precious time.

There is considerable variation in the physical layout, need for sedation, types of MRI procedures, and sedation services across the globe, and hence, there is no standard way to provide anesthesia or sedation care in MRI.

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Airway Emergencies and Safety in Magnetic Resonance Imaging (MRI) Suite, Cont'd.

From “Airway Emergencies,” Preceding Page

Airway emergency response in MRI may look somewhat different in each hospital. Key components of a comprehensive plan for safe emergency care in MRI involves partnering with the radiology department to determine the safety of equipment available for use in Zone IV, and a resuscitative area outside of, but not far from Zone IV. The Standard Operating Procedures and Hospital Policy for managing emergencies in MRI should be revisited as new guidelines emerge or demands for anesthesia services in MRI change. Simulations can help to insure the entire team can safely manage patient emergencies in Zone IV.

Routine availability of MR-safe-conditional laryngoscopes and other airway equipment in the MR environment will avoid inadvertent entry of MR-unsafe devices into Zone IV. This may involve purchasing additional equipment to maintain safety in the MRI environment. Injury to patients, staff, or MRI scanners is both unacceptable and expensive. As anesthesia care and complexity of patients continues to increase in the MRI suite, it is necessary to maintain vigilance for the distinct hazards present in the MR environment and create systems that protect our patients and staff from tragic but preventable accidents. MRIs cannot be easily shut down, and “quench” is an expensive and potentially dangerous operation. Consistent safety standards should be followed in all non-operating room locations, intraoperative MRI scanners or free-standing radiologic centers where anesthesia is provided. MRI safety is both an institutional and an individual responsibility.

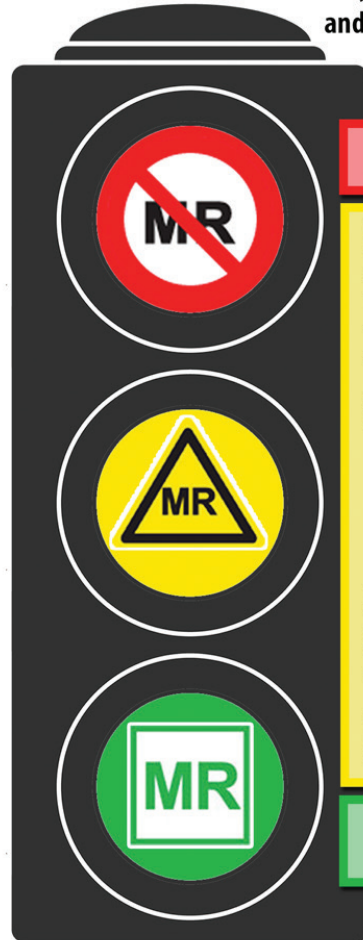
Dr. McClung is an assistant professor in the Department of Anesthesiology and Critical Care Medicine, Children’s Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

Dr. Subramanyam is an associate professor in the Department of Anesthesiology and Critical Care Medicine, Children’s Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

The authors have no conflicts of interest.

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices and accessory medical devices. Implants, medical devices and other equipment used in or near the MR environment should be labeled as **MR Unsafe**, **MR Conditional**, or **MR Safe**.



MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.

MR Conditional items may safely enter the MRI scanner room only under the very specific conditions provided in the labeling. Patients should not be scanned unless the device can be positively identified as MR Conditional AND the conditions for safe use are met.

The conditions for safe use will be different based on the intended use of the device.

For **items intended to enter the bore of the MRI system**, the MRI Safety labeling should be matched with the MRI system for:

- Static field strength
- Maximum spatial field gradient
- dB/dt limitations (usually only applicable to active implants)
- SAR limits
- Any other conditions needed for safe use of the device, for example restrictions on the types of coils that may be used

When present, information about expected temperature rise and artifact extent may inform the risk/benefit decision of whether or not a patient should undergo an MRI examination. Expected temperature rise and artifact extent information are not conditions that must be met.

Items NOT intended to enter the bore of the MRI system usually have gauss line positioning restrictions or requirements to tether or affix the device to an unmovable part of the room.

MR Safe items pose no safety hazards in the MR environment. They may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.



Figure 1: United States Food and Drug Administration. Understanding MRI Safety Labelling. <https://www.fda.gov/media/101221/download> Accessed on Dec 7, 2019.

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APSF Awards 2020 Grant Recipients

by Steven K. Howard, MD

The APSF's Investigator-Initiated Research Program supports the Mission Statement that includes the goal to continually improve the safety of patients during anesthesia care by encouraging and conducting safety research and education. The APSF has funded over 9 million dollars on patient safety research since 1987 to help achieve these goals. This year's grants get at the heart of two long-standing anesthesia-related safety issues: malignant hyperthermia and evaluation of the airway.

The 2019–20 APSF Investigator-Initiated Research Grant Program received 27 letters of intent submitted in early February 2019. After a thorough evaluation, five teams were invited to submit full proposals. On October 19, the Scientific Evaluation Committee met in Orlando, FL, during the American Society of Anesthesiologists national meeting to make funding recommendations to the APSF Board of Directors. Two recommendations were reviewed and subsequently accepted.

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



Sheila Riazi, MSc, MD, FRCPC

Associate Professor, Department of Anesthesia, University Health Network, University of Toronto, Toronto, Canada

Dr. Riazi's proposal is entitled "*A Minimally Invasive Diagnostic Test for Malignant Hyperthermia.*"

Background: Malignant hyperthermia (MH) is a potentially fatal hereditary disorder that is induced by certain anesthetics. Although rare, a malignant hyperthermia crisis is one of the most feared adverse anesthetic outcomes because

1 in 10 patients die and 1 in 3 experience complications.^{1,2} Thus, preventing exposure to triggering anesthetics is crucial in patients who are susceptible to MH. However, screening patients for MH remains challenging as genetic testing identifies only half of all susceptible individuals.² The current standard diagnostic test for MH susceptibility—the caffeine-halothane contracture test (CHCT)—is sensitive (97–100%) but invasive and costly. Furthermore, it requires travel to one of the few specialized centers worldwide because the test must be completed within 5 hours after the muscle biopsy. Therefore, only about 4% of those with suspected MH susceptibility undergo the standard diagnostic test.³

The calcium-induced calcium release (CICR) test is an alternative, less-invasive means to diagnose MH susceptibility. Unlike the CHCT, the CICR test requires a small muscle sample that could be harvested in a physician's office and shipped for analysis at a specialized testing center up to 72 hours after the biopsy. In addition to these advantages, the CICR test is the standard for MH susceptibility diagnosis in Japan, despite lacking rigorous validation against the standard CHCT.⁴ Our MH testing center is currently the only site worldwide with the expertise to conduct both the CHCT and the CICR test, placing our research team in an advantageous position. We therefore propose a single-center, prospective cohort study to validate the alternative CICR test against the standard CHCT by performing both tests simultaneously in samples from every patient referred to our center.

Aims: Our overall goal is to demonstrate that the alternative CICR test is a suitable replacement for the standard CHCT for diagnosing MH susceptibility. Given the advantages of CICR over CHCT, our primary aim is to evaluate whether the sensitivity of the alternative CICR test is greater than 80%, using the CHCT as the reference standard. Our preliminary data have proved the feasibility of CICR and have shown promising results.

Implications: This research will be the first to validate CICR against CHCT, taking advantage of our unique position as the only laboratory worldwide with expertise in both tests. Not only could this work increase use of a less expensive and less invasive diagnostic test, it could also increase the uptake of MH-susceptibility testing beyond the current 4%, ultimately improving patient safety.

Funding: \$137,449 (January 1, 2020–December 31, 2021). This grant was designated the

APSF/ASA Presidents' Research Award. Dr. Riazi is also the recipient of the Ellison C. "Jeep" Pierce, Jr., MD, Merit Award, which provides an additional, unrestricted amount of \$5,000.

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Scott Segal, MD

Thomas H. Irving Professor and Chair,
Department of Anesthesiology
Wake Forest School of Medicine

Dr. Segal's project is entitled "*Development of machine learning algorithms to predict difficult airway management.*"

Background: Successful airway management is fundamental to safe anesthetic performance, and airway management failure continues to be the one of the leading causes of anesthesia-related death and severe morbidity.¹ While preoperative airway assessment is considered the worldwide standard of care, 75–93% of difficult intubations are unanticipated, and all easily performed airway examination systems in clinical practice perform only modestly to detect difficult intubations.² We propose to create a machine learning system

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2020 Grant Recipients

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based on analysis of facial photographs which could outperform conventional bedside tests and human experts and improve airway management and patient safety. Previous work by our group has demonstrated that an algorithm based on supervised (i.e., human-assisted) computer analysis of facial images combined with thyromental distance (TMD) can outperform classical bedside tests and human experts.³ Here we propose to extend this work by the development of completely unsupervised computer algorithms based on feature extraction from facial photographs by convoluted neural networks (CNNs).

Aims: CNN technology already exists for highly accurate deterministic feature extraction of frontal views of the face and is widely employed in facial recognition applications. We will develop a similar CNN-based feature extractor from profile views of the face, which likely contains important information about potential intubation difficulty (Aim 1). We will then fuse this information with frontal facial information and patient demographics and bedside airway data (TMD and Mallampati class [MP]) and train an advanced algorithm to classify faces as easy- or difficult-to-intubate based on prospective observation of ground truth during induction of general anesthesia (Aim 2). We will compare performance of the derived algorithm to MP+TMD in both the derivation dataset as well as an independent validation dataset. We will test the hypothesis that the computer-derived algorithm will outperform classical bedside tests and improve prediction of difficult intubation. Finally, we will build a smartphone-based data entry tool to capture photographs, patient demographic information, and bedside airway examination data and transmit it to an HIPAA-compliant, encrypted online database (Aim 3). This will form the basis of a future completely automated airway prediction tool, based on our methods derived in this investigation.

Implications: Airway failure is still the #1 cause of anesthesia-related mortality, and most difficult intubations are unanticipated, but there are well-established guidelines and ever-expanding options for the management of the

anticipated difficult airway.⁴ Therefore any improvement in airway prediction is likely to improve patient safety. Failed airway management is even more common outside the OR, and the safety improvement may be even more profound in the emergency department, ICU, or prehospital setting. Our proposal is closely aligned with the APSF's current funding priorities, as it involves large numbers of patients, including the healthiest, uses advanced information technology to prevent harm, and focuses on a low-frequency but devastating complication, difficult or failed intubation. In the future, prediction of difficulty with additional aspects of airway management, including bag-mask ventilation, could also be modeled. The data entry tool could be coupled to a cloud-based feature extraction and prediction calculator, returning a prediction to end-users.

Funding: \$150,000 (January 1, 2020–December 31, 2021). This grant was designated the APSF/Medtronic Research Award.

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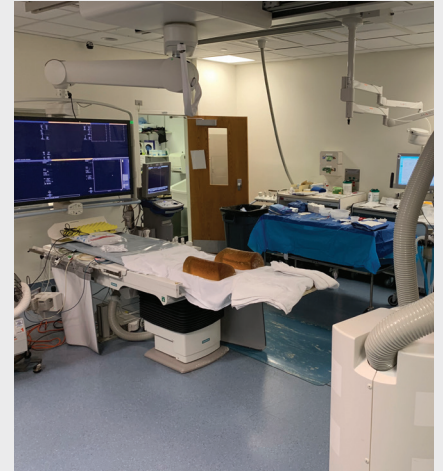
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The APSF would like to thank the above researchers and all grant applicants for their dedication to improve patient safety.

Dr. Howard is staff anesthesiologist at the VA Palo Alto Health Care System, professor of Anesthesiology at Stanford University School of Medicine and chair of the APSF Scientific Evaluation Committee.

Dr. Howard serves on the Board of Directors of the APSF and has no other conflicts of interest to declare.

APSF Stoelting Conference 2020



"Addressing Crucial Patient Safety Issues in Office-Based and Non-Operating Room Anesthesia (NORA)"

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September 9–10, 2020
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For registration and conference inquiries, please contact

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RAPID Response

to questions from readers

An Incident of GlideScope® Stat Cover Failure

by Martha Hensley, DNAP, CRNA

Dear Rapid Response,

GlideScope® Stat Tip Breaks in Patient's Airway

I would like to present a scenario in which the tip of a disposable GlideScope® Stat cover inadvertently broke off in a patient's airway. Figure 1 depicts an intact Verathon GlideScope® (North Creek Parkway, Bothwell, WA) Stat cover.

A 76-year-old, 62 in., 60 kg, ASA class 3, woman presented for an elective direct laryngoscopy with biopsy due to a neoplasm at the base of the tongue. Video laryngoscopy was performed at the request of the Ears, Nose, and Throat (ENT) surgeon with the GlideScope® positioned midline using a Stat 3 cover by the student registered nurse anesthetist (SRNA), with the certified registered nurse anesthetist (CRNA) and ENT surgeon in attendance. The surgeon assessed the airway structures and vocal cords while the GlideScope® was still in place. No other instruments were placed in the airway. Thereafter, the patient was intubated with a 6.0 endotracheal tube without complication. The correct position of the endotracheal tube was verified by presence of ETCO₂ and bilateral breath sounds, and the patient was placed on volume control mechanical ventilation. The case proceeded without difficulty.

At the end of the procedure, the surgeon identified a foreign object in the airway, which was removed with graspers. After further inspection, it was obvious that the clear plastic object was the distal tip of the disposable Verathon GlideScope® Stat cover. The distal one-third of the tip of the Stat cover had fractured off in the patient's airway (Figure 2,3). The patient was successfully extubated and transferred to the post anesthesia care unit (PACU) in stable condition. PACU recovery was uneventful. No bleeding, edema, or complaints of sore, scratchy throat were elicited from the patient. The patient was discharged to same-day surgical services without further incident. An incident report was filed with the facility's risk management team, and the CRNA contacted the GlideScope® company about the incident.

DISCUSSION:

In reviewing the literature, GlideScope® cover defects and failures are rare events that occur during intubation.^{1,3} Nevertheless, it is imperative that the anesthesia professional be

cognizant of potential equipment failures when utilizing video laryngoscopy, as GlideScope® blade fractures can lead to disastrous consequences (e.g., migration of the fractured tip into the lungs, perforation of the esophagus or trachea) for the patient. One hypothesis that might explain this occurrence is that the fracture occurred from a manufacturing flaw or damage during production or shipment. According to Verathon Medical, eight blade failures have occurred from 2007–2012.¹ Only two cases have been published. Due to the limited information available since 2012, there is a need for further research on the design and durability of the distal tip of GlideScope® Stat blade covers. All three fractures (this case and the two published cases) occurred at the distal tip. The published cases of GlideScope® cover failure describe the use of upward, rotational force to reposition the blade.^{2,3} In this case, the blade was positioned midline with no upward or rotation force required. It is unclear, from Verathon Medical, where the fracture occurred in the other 6 cases reported to the company. There is no updated information, since 2012, to determine if this is an ongoing problem or if the incidents remain isolated.

This personal experience of an equipment malfunction involving the GlideScope® notwithstanding, video laryngoscopy remains a reliable option for difficult airways and routine procedures. However, caution should be used to carefully inspect the GlideScope® Stat cover for any defects or breakage before and after each use—especially at the distal tip.

Martha Henley is a certified nurse anesthetist at Lonesome Pine Hospital in Big Stone Gap, VA.

She has no conflicts of interest to disclose.

Reply:

The content of this letter was shared with Verathon, the manufacturer of the GlideScope® video laryngoscope who provided the following information for readers.

- Verathon maintains a robust and compliant quality management system including a complaint and vigilance reporting system. We take all complaints seriously. Complaints can be reported directly to our Customer care team at +1-800-331-2313.
- GlideScope STATs maintain less than 2.1 ppm

(parts per million, 0.00021%) failure rate for a broken tip.

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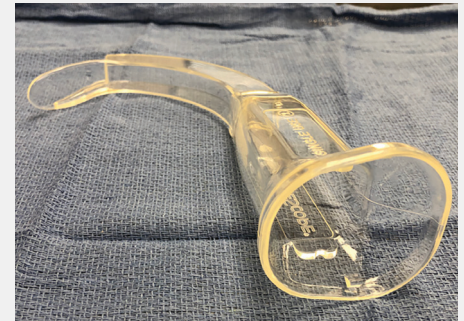


Figure 1: Depicts an intact Verathon GlideScope® Stat cover.

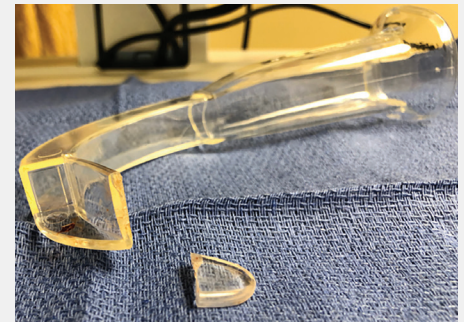


Figure 2: Depicts broken tip of GlideScope® Stat cover.

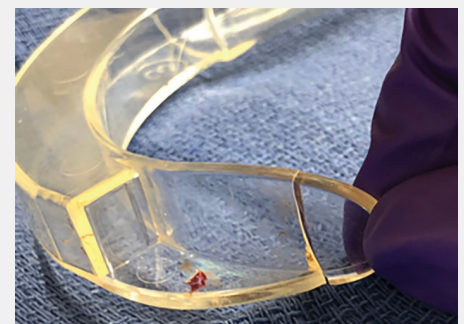


Figure 3: Depicts broken tip of GlideScope® Stat cover.

Portable Point of Care Ultrasound (PPOCUS): An Emerging Technology for Improving Patient Safety

by Patrick Lindsay, MB, BS; Lauren Gibson, MD; Edward A. Bittner, MD, PhD; and Marvin G. Chang, MD, PhD

INTRODUCTION

Many of the technological advancements adopted by our specialty such as the pulse oximeter, capnography, brain function monitoring, and video laryngoscopy have revolutionized patient care and safety and have been adopted by other clinicians involved in acute care. In the recent past, there was heated debate, including in this *Newsletter*,¹ regarding the impact of ultrasound in increasing patient safety for the placement of central lines and nerve blocks. Similarly, we believe that Portable Point of Care Ultrasound (PPOCUS) which involves the use of handheld, portable, affordable, easy-to-use ultrasound devices to perform point of care ultrasound (POCUS) is an emerging technology that has the potential to improve perioperative patient safety.

PPOCUS is undergoing a revolution similar to what computing technology experienced in the 20th century, an acceleration in the development of portable, efficient, and affordable systems. Ultrasound technology has evolved to the point that portable ultrasound devices can

now fit seamlessly in a clinician’s back scrub pocket (Figure 1) at a price point as low as \$2000 USD. Furthermore, the imaging capabilities far exceed many of the best ultrasound machines of decades ago.

The revolution in PPOCUS is facilitated not just by the portable nature of the hardware of current pocket-sized ultrasound devices, but also by the software available to support the user and its adoption. Many of the conventional ultrasound devices require rudimentary methods such as USB cables to download and store images. However, the newer PPOCUS devices are now able to directly upload acquired images to the cloud via WiFi or cellular network. This new technological capability can seamlessly be integrated into the Picture and Archiving Communication System (PACS) and patient’s electronic medical record system. PPOCUS studies are able to be de-identified with a single click² in order to maintain patient privacy and confidentiality. However, specific institutional guidelines to protect patient privacy regarding storing this information is variable

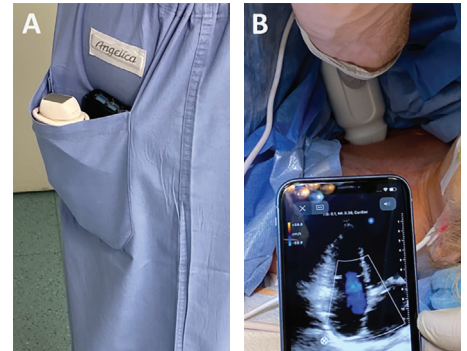


Figure 1: Extreme portability afforded by portable ultrasound devices (Panel A) and use of PPOCUS in perioperative settings such as in the operating room (Panel B).

throughout the US. Nevertheless, this easy integration that meets HIPAA-compliant standards allows for immediate collaboration with other health care providers as well as providing new real-time opportunities for quality assurance of the studies obtained. In addition, some of the handheld devices have novel teleguidance technologies that allow ultrasound experts to guide novice ultrasound users through an ultrasound exam remotely and allow for live image acquisition, interpretation, and feedback.³ Artificial intelligence is expected to further facilitate image acquisition and interpretation, providing real-time clinically relevant capabilities such as the determination of left ventricular function and the presence of pulmonary edema.

INDICATIONS AND LIMITATIONS OF PPOCUS

The increased accessibility of PPOCUS devices has allowed for its meaningful use in a variety of patient care situations where perioperative ultrasound may impact patient outcomes.⁴ In our practice at the Massachusetts General Hospital (MGH), we have adopted handheld ultrasound devices within all perioperative domains to make time-sensitive diagnoses, perform serial assessments, and guide important management decisions. Table 1 shows the many indications for the perioperative use of PPOCUS by anesthesia professionals. Table 2 compares PPOCUS with POCUS which highlights many of the advantages and limitations of this technology.

FACILITATING ADOPTION AND COMPETENCY FOR PPOCUS

Widespread adoption of a new technology like ultrasound can be daunting due to lack of

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Table 1: Emerging Indications for PPOCUS Use by the Anesthesia Professional

<ul style="list-style-type: none"> • Environments with significant time constraints, production pressure, and limited space (i.e., preoperative bay, for instance after a regional block, preoperative evaluation clinic, OR, OB, PACU, ICU, and floor)
<ul style="list-style-type: none"> • Qualitative assessment using a focused binary decision-making approach sufficient to answer the clinical question (i.e., Is there severely reduced LV function? Yes or No)
<ul style="list-style-type: none"> • Facilitate preoperative evaluation when a preoperative echo is desired but has not been obtained to avoid significant case delays and cancellations associated with obtaining a formal echo study
<ul style="list-style-type: none"> • Confirm clinically significant physical exam findings (i.e., undocumented murmur consistent with aortic stenosis)
<ul style="list-style-type: none"> • Ultrasound guidance of procedures such as IV access, CVC and arterial line placement, regional blocks, thoracentesis, paracentesis, cricothyroidotomy
<ul style="list-style-type: none"> • To perform emergent lifesaving procedures in nonideal conditions (e.g., placing arterial line under the drapes in a crashing patient, on a hospital floor in a patient’s room, or in a non-operating room procedural area)
<ul style="list-style-type: none"> • Differentiating between various types of shock
<ul style="list-style-type: none"> • Quickly ruling out life-threatening pathology (i.e., tamponade, pneumothorax, and pulmonary embolism) in critically unstable patients
<ul style="list-style-type: none"> • Verifying endotracheal vs. esophageal intubation during cardiac arrest when capnography may not be a reliable indicator of endotracheal intubation¹³
<ul style="list-style-type: none"> • Differentiating PEA vs. pseudo-PEA during cardiopulmonary arrest
<ul style="list-style-type: none"> • Optimizing left and right heart function while avoiding invasive procedures and monitors (i.e., PA line, TEE) and their associated complications
<ul style="list-style-type: none"> • Rapid evaluation and assessment of volume status in critically unstable patients¹⁴⁻¹⁶
<ul style="list-style-type: none"> • Assess gastric volume to determine aspiration risk
<ul style="list-style-type: none"> • Evaluation for pulmonary edema or pneumothorax to facilitate optimization in the perioperative period

PPOCUS May Answer Clinical Questions Rapidly

From “PPOCUS,” Preceding Page

familiarity, formal training, or a conditioned reliance on formal services staffed by cardiologists and cardiac anesthesiologists. Surveys of anesthesiologists have revealed the fear of missed diagnoses and the lack of formal training or certification as important barriers to the adoption of focused TTE in their practice.⁵ Understandably there are many who may be concerned about the medical/legal ramifications of “nonexperts” performing PPOCUS. This is a valid concern for both users and hospital administrators. However, it is reassuring that the known malpractice lawsuits to date have related not to the misdiagnosis and misinterpretation of POCUS, but rather to the entire lack or delay in the use of POCUS.⁶⁻⁸

At MGH, PPOCUS was initially employed by ultrasound enthusiasts who were looking to be self-reliant in evaluating and rescuing their own patients before things “spiraled out of control.” Anesthesia professionals who were PPOCUS enthusiasts increasingly began to respond to “anesthesia stats” and emergencies in a variety of clinical arenas in which we practice, and PPOCUS demonstrated its utility to others by answering clinically important questions in a rapid time frame. PPOCUS was shown to be instrumental in the rapid assessments of acute conditions, allowing patients to be rescued even before our formal rescue echo service could be fully mobilized, which helped to facilitate its adoption in the department. Further support for PPOCUS was achieved in our department after it demonstrated its utility in avoiding unnecessary transfer of patients to higher levels of care such as the ICU, resulting in better utilization of limited hospital resources with the rapid identification of reversible causes of deterioration gleaned by clinicians using it.

One of the major advantages of PPOCUS is that it can be readily used by all, without a significant amount of training. Prior studies suggest that physicians with limited prior ultrasonographic experience can gain proficiency in focused ultrasound with limited training, such as a 1-day workshop and as few as 20 practice scans.^{9,10} Of note, the American College of Chest Physicians (ACCP) requires 20 TTE studies to earn the certificate of completion for POCUS. The American College of Emergency Physicians (ACEP) requires a minimum of 25 studies per imaging application. Similarly, the Society of Point of Care Ultrasound recommends a minimum of 25 studies for certification in POCUS. Similar competencies might be developed for PPOCUS.

Table 2: Summary of the similarities and differences of POCUS with portable ultrasound devices (PPOCUS) compared to conventional ultrasound platforms

Characteristic	PPOCUS	Conventional US
Cost	\$2,000 to \$12,500	\$30k to 100k+
Portability/space requirements	Extreme portability/Devices can fit in a scrub pocket and many weigh less than a pound	Not always portable/Devices may weigh up to hundreds of pounds
Bootup time	Seconds	Up to minutes
Time to successful deployment and use	Quick, given extreme portability	Slow, given labor intensive to mobilize
Electrical outlet requirement	No	Some
Quality of imaging	Good enough for binary decision-making	Generally higher quality imaging
EKG synchronization capability	No	Yes
Ability to use in situations where space is limited	Yes	No
Transesophageal echocardiography capability	Not presently	Yes
Potential for disruption to ongoing critical care support (i.e., chest compressions)	Low	High
Wireless and/or 3G integration with the PACS	Some	Some
Allows for quick de-identification of studies to facilitate external collaboration	Yes	No
Teleguidance and AI capability to facilitate data acquisition, interpretation, and collaboration	Many	Limited
Knobology (or the functionality of controls on ultrasound device)	Limited, which may facilitate use by novice users	Extensive, which may complicate use
Ability to use M-mode and color doppler	Yes	Yes
Ability to use PWD, CWD, and TDI	No	Yes
Integration with EMR, PACS	Many	Most

Abbreviations: Artificial Intelligence (AI), Continuous Wave Doppler (CWD), Electronic Medical Record (EMR), Picture Archiving and Communication System (PACS), Pulse Wave Doppler (PWD), Tissue Doppler Imaging (TDI), ultrasound (US)

RECOMMENDATIONS AND STRATEGIES TO FACILITATE PPOCUS USE

Our PPOCUS philosophy is that “anyone can do it”—not just cardiac anesthesiologists and cardiologists. Our educational strategy has been to target clinicians that are interested in implementing this technology in their daily practice and subsequently champion its use throughout the department. PPOCUS is ideal for ultrasound education because the “activation energy”

required to teach novice users ultrasound skills, and for novice users to practice those skills, is significantly reduced due to the extreme portability, affordability, and ease of use.

At the MGH, we have found that PPOCUS has helped to facilitate ultrasound training of over 40 anesthesia professionals over the last 6 months without requiring significant departmental support

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Limited Training May Be Required To Use PPOCUS

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and a formalized structured training program. While we have formal training modules available, we do not initially require their use so as to avoid dissuading the learners before they've had enough hands-on training with an expert to develop some self-confidence and enthusiasm applying the new skill in clinical practice. Enthusiastic novice users often find their own interesting resources (i.e., YouTube, podcasts, websites, etc.) to facilitate their self-learning, independently practice on our high fidelity TTE simulator, and perform a minimum of 5–10 studies one-on-one with an expert user until they are able to adequately perform a limited study on their own. Most achieve competence in obtaining the standard cardiopulmonary views (parasternal long axis, parasternal short axis, apical four-chamber view, subcostal four-chamber view, IVC view, and lung ultrasound) within 20 studies that are performed in a short period of time (within a month). We attempt to facilitate access to portable ultrasound devices so that learners can sustain the momentum necessary to achieve rapid growth of their POCUS skills. Interestingly, many of the clinicians most receptive to learning PPOCUS are early in their anesthesia training (i.e., CA-1). We hope that the junior anesthesia trainees will go on to train both the current and the next generation of anesthesia professionals so that our entire department will become experts in POCUS.

CONCLUSION

The incorporation of PPOCUS into perioperative care seems inevitable given its potential to enhance patient safety. It is therefore important to consider the optimal means of incorporating

this technology into clinical practice and ensuring that it is used correctly by building appropriate training curriculums. For example, early targets for implementation might include integration into simulation training, emergency manuals, residency training programs, and perioperative domains where feasible. Our specialty, which has been a pioneer in patient safety should promote proficiency in PPOCUS similar to the field of emergency medicine over a decade ago.^{11,12} Anesthesia professionals should embrace and innovate its use as a new paradigm for patient safety and education in perioperative medicine.

Dr. Lindsay is a resident in the Department of Anesthesia, Critical Care, and Pain Medicine at the Massachusetts General Hospital, Boston, MA.

Dr. Gibson is a resident in the Department of Anesthesia, Critical Care, and Pain Medicine at the Massachusetts General Hospital, Boston, MA.

Dr. Bittner is an associate professor in the Department of Anesthesia, Critical Care and Pain Medicine at the Massachusetts General Hospital, Boston, MA. He is an associate editor of the APSF Newsletter.

Dr. Chang is the assistant program director of the Critical Care Anesthesiology Fellowship and a member of the faculty in the Department of Anesthesia, Critical Care and Pain Medicine at the Massachusetts General Hospital, Boston, MA.

The authors do not have any disclosures.

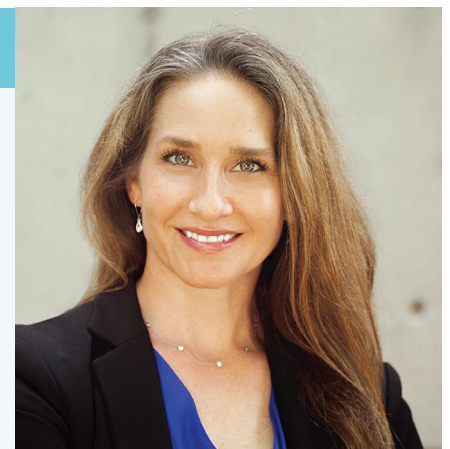
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Q & A

Navigating Perioperative Insulin Pump Use

Q Dear Q&A,

Over the last decade, patients with insulin-requiring diabetes are increasingly using continuous subcutaneous insulin infusion (CSII) pumps. These pumps fundamentally provide continuous insulin to meet basal requirements with the ability to manually bolus additional insulin. Increasing sophistication has added continuous subcutaneous glucose monitoring (CGM) and insulin delivery driven by CGM (e.g., Minimed™ 670G, Medtronic, Northridge, CA). CSII pumps are commonly used in the perioperative period to provide insulin therapy based upon institutional guidelines.^{1,2} In a recent literature search, one published criterion to guide utilization of more sophisticated devices and automated features was found.³ Long et al. suggested that the pump should run intraoperatively. States with altered perfusion, shock, hypothermia, technical problems, and very high or low glucose values are determinants for discontinuing the device.³

The Minimed™ 670G is a hybrid closed loop system (HCLS). In the AutoMode, the pump uses CGM to automatically adjust basal and correctional insulin delivery while the patient manually selects prandial boluses. Patients can disable the AutoMode in temporary favor of Manual Mode. (In the Manual Mode, pre-programmed continuous basal insulin delivery remains, but both the prandial and correctional insulin boluses are calculated and acknowledged first by the patient). Although this hybrid closed loop system has been applauded as a huge technology advance, there are challenges to using it. Goodwin found that over one-third of the 83 patients studied abandoned use of the 670G due to “calibration requirements, problems with sensor durability or adhesion, skin irritation, and forced exits from AutoMode.”⁴

In AutoMode, near continuous interstitial glucose readings (every 5 minutes) automatically alter insulin delivery toward a pre-programmed blood glucose target. This automated functionality raises questions about its safety in the anesthetized patient.

1. Is the AutoMode able to more precisely mitigate or correct for blood glucose derangements than an anesthesia professional who adheres to institutional guidelines on perioperative insulin pump management?
2. Can AutoMode better abate surgical stress hyperglycemia?



3. Is there an increased likelihood that anesthesia professionals must identify and respond to device alarms?
4. Is special training required if anesthesia professionals are to use these pumps safely?
5. How reliable is CGM technology? CGM interstitial values lag behind blood glucose values. Some CGMs lose accuracy with certain medications, including acetaminophen. CGMs are not recommended for decision-making in the inpatient setting.⁵

Hybrid closed-loop systems are a new rapidly developing technology with little in the literature to guide their perioperative use. Indeed, it is quite possible that some surgeries are being performed in AutoMode without the knowledge of the anesthesia professional. With a high glucose result, the anesthesia professional may bolus a correctional subcutaneous or IV insulin dose via syringe, while at the same time the AutoMode has increased insulin delivery via the insulin pump.

I realize that an hourly point-of-care blood glucose measurement is a key safety factor when caring for a patient receiving insulin therapy while anesthetized. With HCLS technology likely to proliferate, it would be helpful to have recommendations on the use of AutoMode and similar automatic modalities in the perioperative period for inclusion in our institution's Perioperative Insulin Pump Guidelines.

*Thank you for your time.
Tamra Dukatz, MSN, CRNA
Beaumont Health, Royal Oak, Michigan*

Ms. Dukatz has received an investigator initiated grant from Sanofi, US, for her co-authored work entitled “Insulin glargine dosing before

next-day surgery: comparing three strategies.” Journal of Clinical Anesthesia. 2012; 24: 610–617.

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A Response:

Increasing numbers of patients are using insulin pumps and require anesthetic care, and therefore, the concerns raised by the author above in her letter are timely and worthy of consideration. The growth in adopting continuous subcutaneous insulin infusion (CSII) technology is a testament to the added convenience and quality of glucose control this technology affords patients. These advantages can be just as useful in the perioperative period as they are in the outpatient setting. With improvements and advances in pump technology, including the hybrid closed-loop system (HCLS), glucose management is transitioning from an active responsibility of the anesthesia professional to a (semi-)automated process.¹

Before addressing specific questions about HCLS for glucose management, it is worthwhile to consider the benefits of maintaining CSII in the perioperative setting as compared to provider-managed glucose control. CSII-controlled insulin at a basal rate is personalized to provide the closest possible physiologic replacement for the patient's nonfunctional pancreas. Although it is yet to be studied scientifically, switching to a previously untested empiric strategy abruptly prior to surgery is intuitively less ideal than continuing the method or technique that has been optimized for the patient.

See “CSI Pumps,” Next Page

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

CSI Pumps Deliver Very Accurate Insulin Doses

From “CSI Pumps” Preceding Page

Furthermore, insulin pumps can deliver doses of insulin with a precision of 0.1, or even 0.05 units. This degree of precision cannot be achieved by providers. Administering intraoperative insulin boluses for hyperglycemia via the pump is the optimal way to administer an exact dose, particularly in pediatric patients who may be exquisitely sensitive to small doses of insulin.^{2,3}

The physiologic benefits notwithstanding, patients (and their families) with insulin pumps are generally extremely “connected” to their pumps and are skeptical when medical providers insist on removing their pumps prior to a procedure. Online discussions are replete with complaints from patients who were “forced” to remove their insulin pumps for surgery and strongly worded advice to resist relinquishing insulin management to the anesthesia team. The willingness to work together with the patient to continue insulin pump therapy throughout the perioperative period is invaluable in establishing rapport and alleviating fear and anxiety.

Returning to the HCLS issues, device alarms mainly fall into two categories: notifications of extreme blood sugar changes (e.g., warnings of rapid change, approaching high/low limits, high or low blood sugar) and insulin pump/CGM system requests (e.g., low reservoir, calibration required, weak or poor signal). The former type is clinically useful, although confirmation by fingerstick with the facility’s own blood glucose monitor before intervention is recommended. System requests for reservoir refill or calibration can usually be avoided or reduced by instruct-

ing the patient to replace the infusion set with a full reservoir 12–24 hours before anesthesia and to calibrate the sensor no more than six hours before the anesthetic.

Automated insulin administration is designed with safety in mind. Medtronic’s AutoMode does not deliver a basal infusion; rather, the algorithm determines whether to give a “microbolus” based upon CGM readings and trends every five minutes.⁴ The pump will not deliver a bolus to correct hyperglycemia, but will increase the microbolus dose to an algorithmically determined maximum in response to a rising blood sugar. Concomitantly, it will reduce or withhold microboluses in response to declining blood sugar, so the likelihood of hypoglycemia due to AutoMode is low. Ideally, manual correction boluses should be delivered via the insulin pump both for the safety concerns mentioned earlier and so that the HCLS will be able to incorporate the additional insulin into its algorithm.

Training may be required to use these pumps effectively but they are not complex devices. Despite the advanced technology that these insulin pumps rely upon, managing and using the pump is actually quite simple. In fact, young children are able to use their insulin pumps independently, and an anesthesia professional should be able to quickly learn how to read the pump screen, administer manual boluses, or suspend insulin delivery. The pump’s home screen will display important information, including current CGM reading, active insulin therapy, and Automode status. Programming a bolus requires just a few presses of the button to open the menu and enter the Bolus activity.

The calculated bolus (based on entered blood sugar) will display and must be confirmed before delivery. Although the pumps are easy to learn, when confronted with one, if a provider is unsure how to manage it, endocrinology consultants can be enlisted to assist with the proper use of these pumps. The patient or patient’s family can also demonstrate the features to the anesthesia professional and quick-start guides are readily available on the manufacturer’s website if needed. Guidance for perioperative use of these pumps is typically institutional specific, but may include collaboration with the primary care physician and/or endocrinologist.

One important caveat is that the pump must be located to afford access by the anesthesia professional during the procedure. Additionally, the infusion set cannot be located within the surgical field, and patients should be instructed in advance to insert their infusion set in an appropriate site. There may be situations where the infusion pump location is impractical and continued usage of CSII may not be possible. An alternative management plan should be prepared in conjunction with the patient’s endocrinologist and diabetes management team in that scenario. Table 1 depicts the author’s suggested principles to guide a perioperative institutional policy for patients with insulin pumps.

Just as anesthesia professionals have learned to manage devices like pacemakers or implanted pumps that benefit patients, we should embrace insulin pump technology to provide ideal perioperative care to our patients.

Ari Y. Weintraub, MD

Children’s Hospital of Philadelphia; Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

Dr. Weintraub has no disclosures to report.

Table 1: Author’s suggested principles to guide an institutional policy for patients with insulin pumps in the perioperative period

1. Blood sugar monitoring should be performed for all insulin-dependent patients in the perioperative period regardless of the method of providing insulin therapy.
2. The patient’s insulin pump should continue to be used unless there is an absolute contraindication (e.g., the MRI environment, setting of diabetic ketoacidosis requiring IV insulin and fluid management, shock, marked hypothermia, vasopressor use, severe dysglycemia).
3. Relative contraindications such as the infusion set being in the surgical field and theoretical risk of electrical injury from electrocautery in patients with metal needle infusion sets can be addressed by instructing the patient to place a plastic infusion set in an alternative site. The pump should be shielded with a lead apron when ionizing radiation is used.⁵
4. If the patient uses a pump with HCLS, the automatic mode should be continued with frequent monitoring of the pump’s glucose measurements and close attention to pump alarms. If the CGM indicates hyper- or hypoglycemia or quickly changing blood sugar, confirmation by fingerstick or other reliable technology should be performed to guide clinician intervention. Use of the HCLS may not be appropriate in states of altered perfusion, shock, or hypothermia.⁵
5. When insulin boluses for treatment or correction of hyperglycemia are required, the insulin pump should be used to deliver a precise dose and to maintain the accuracy of the HCLS algorithm when applicable.
6. Consultation with endocrinology or other resources should be sought as needed to help with pump operation.

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How Can We Tell How “Smart” Our Infusion Pumps Are?

by Tim Vanderveen, PharmD, MS; Sean O'Neill, PharmD; and JW Beard, MD, MBA

INTRODUCTION

Medication errors are a leading cause of patient harm in hospitals and operating rooms. Greater than 50% of medication errors that lead to patient injury occur during the medication administration phase.¹ Historically, medication infusion devices served simply as a mechanical device to infuse medications intravenously. The advent of smart infusion pumps allowed for clinical decision support tools to be integrated into the medication administration process. This decision support in smart infusion pumps includes minimum and maximum alerts for dose, concentration, duration, and rate alerts and is part of the dose error reduction software (DERS) that exists in the majority of infusion pumps on the market today. This decision support can prevent misprogramming of pumps or keystroke errors (examples of this type of error would be programming 55 mg instead of 5 mg).

Smart pumps with drug libraries have increasingly gained adoption in acute care patient settings including the perioperative area. A survey completed in 2017 by the American Society of Health System Pharmacists (ASHP) identified that 88.1% of hospitals have adopted smart infusion pumps. This was a substantial increase from 2005 when only 35% of hospitals reported using smart infusion pumps.²

In 2010, over 100 stakeholders were invited to attend an APSF-sponsored medication safety conference to develop new strategies for improving medication safety in the operating room. The output of that meeting was a paradigm that focused on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). Key recommendations from this meeting involved: 1) ensuring that all medication and fluid infusions are administered via a smart infusion device; and 2) facilitation of adequate training and improved standardization of smart infusion pumps.³ A subsequent 2018 APSF Stoelting Conference on medication safety recommended developing consensus between professional and patient safety organizations on standardization of drug concentrations used in infusion administration.⁴

CHALLENGES AND BARRIERS TO SUCCESSFUL USE OF SMART PUMPS

There are a variety of challenges and barriers to achieving 100% adoption of smart infusion pumps.⁵ These challenges include:

1. **Usability and workflow barriers**—Not using the smart infusion pumps or using them incorrectly diminishes their value in reducing medication administration errors. Virtually all infusion pumps in the acute care setting now contain DERS. They also contain the ability to bypass this decision support. Key contributors to noncompliance include outdated interfaces and the ability to easily opt out of



the DERS programming.⁵ Understanding the barriers to compliance with DERS use is the most vital step when evaluating the impact of smart infusion pumps in any organization.

2. **Building and maintaining custom drug libraries**—The drug library which comprises the limits in DERS often need to be created from scratch. This library includes which medications are included as well as the safety alert thresholds for dose, concentration, and duration/rate alerting. The process to build these libraries is time-consuming and resource-intensive. Unfortunately, this resource-intensive process of building a drug library is just the first step. Maintaining and updating this content is of vital importance to achieve optimal results from this technology and if not completed can be an impediment of full smart pump adoption.
3. **Alarm/alert fatigue**—Smart infusion pumps are no different than any other health care technologies in that excessive alerts/alarms can lead to health care provider alarm or alert fatigue.^{6–8}

INTERVENTIONS TO OVERCOME BARRIERS TO SMART PUMP ADOPTION

In 2010, the *APSF Newsletter* reported on a large health system's implementation of smart infusion pumps. Using the paradigm of STPC described above, Wake Forest University Baptist Medical Center was able to successfully standardize infusion-related practices across multiple patient care areas including the operating room. Key interventions leading to success in this implementation included: 1) Multidisciplinary engagement incorporating pharmacy, nursing, intensive care providers, and anesthesia professionals; 2) A focus on standardization of all IV medications concentrations, dosing units, and adoption of smart pump technology across the continuum of care in the organization; and 3) An emphasis on training staff to ensure there was an understanding of the

capabilities and limitations of the infusion devices.⁹

HOW INTELLIGENT ARE SMART INFUSION PUMPS IN YOUR ORGANIZATION?

Infusion pumps collect information ranging from discrete keystroke data to information regarding clinicians' responses to alerts. This data is frequently communicated wirelessly to a central server. However, this data can be challenging to access and interpret and is often underutilized by clinicians that are responsible for the oversight of these devices. The Institute for Safe Medication Practices (ISMP) completed a survey in 2018 to learn about the current utilization of smart pump data analytics. This survey included responses from pharmacists and nurses at 126 hospitals and concluded that 96% of respondents believe that using data from smart infusion pumps was vital to driving quality improvement. However, only 22% of respondents felt that their organization had the correct resources and skills to capture meaningful and actionable insights from this data. ISMP recommended that organizations utilize external resources, such as data companies or infusion pump manufacturers, to assist with data evaluation when needed.¹⁰

WHAT INFORMATION IS CAPTURED IN INFUSION DEVICES?

Conventional Data Evaluation and Compliance with DERS

When clinicians program infusion pumps, they are presented with a choice to either use the DERS or use a “no drug selected” or “basic infusion” mode. When DERS is not utilized, clinicians remove all clinical decision support and safety limits from the process. Most infusion pump devices provide data on the percentage of infusions using the DERS. Clinicians may not realize how often programming errors occur and how often DERS is bypassed. It is vitally important to share this data with frontline clinicians to provide an adequate feedback loop to support continuous quality improvement.

Alert and Alarm Data

Alert fatigue and subsequent severe adverse events have been associated with smart infusion pump use.^{6–8} Alert fatigue is characterized by clinician desensitization to alerts or alarms which can lead to missed clinical alerts, delayed assessment of patients and the potential for serious patient harm.^{11,12} This desensitization occurs due to presence of clinically meaningless or nuisance alerts.¹³

Infusion pump logs capture each alert and the clinician's response to facilitate alert management to reduce fatigue. Infusion pump associated clinical alerts can include minimum

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and maximum alerts for dose, concentration, and duration or rate alerts. Clinician responses can include overriding an alert and proceeding, cancelling the infusions and preprogramming as a basic infusion, or altering the infusion parameters to be within the alert limits. Assessing alert data has value to understand if alert fatigue exists, if limits need adjusting, or if there are potential unsafe practices surrounding specific medications.

MEDICATION PRACTICE STANDARDIZATION

In 2015, ASHP initiated their Standardize 4 Safety campaign.¹⁴ This was the first national, interprofessional effort to help reduce the incidence of medication errors by standardizing medication concentrations. Access and understanding of infusion device data can provide details that can facilitate this standardization. This data includes the following elements of medication administration: 1) the overall usage of specific agents; 2) the location where these medications are administered; 3) the dose and concentrations that were commonly used; and 4) the total volume administered. For example, analysis of infusion pump data might reveal commonly used medications in anesthesia care areas and their concentrations. Having insight into these practices can play a significant role in achieving standardization. Standardizing concentrations and dosing units between anesthesia and inpatient units is a critical element of medication safety as this might reduce the risk of a medication error when a patient transitions from one care area to another (Figure 1).

NOVEL DATA EVALUATION

Infusion pump data describes the total volume of an infusion administered to a patient and may serve to right-size dispensed amounts. For example, if Drug X is dispensed to a procedural area from the pharmacy or an automated dispensing cabinet in 100 mL, how do we know how much of this drug was administered? Traditionally, clinicians have been left to manually examine OR and EHR records to extract this information. However, the data from the infusion devices may provide an additional or more precise measurement of how much medication was administered.

NARCOTIC DIVERSION MITIGATION

The impact of opioid diversion from health care facilities has been widely documented, but vulnerabilities in monitoring the use of controlled substances still exist.¹⁵ ASHP currently recommends implementing a surveillance program, which effectively monitors data from medication technologies in high-risk areas such as the OR.¹⁶ Understanding how much drug is dispensed versus how much is administered to a patient can be vital to a narcotic diversion monitoring program. For example, if fentanyl is dispensed in a 2500 mcg/250 mL bag, the infu-

Figure 1: Smart Pump Considerations for Anesthesia Professionals

- Dose Error Reduction Software (DERS) should be utilized for all medications administered via an infusion pump
- Anesthesia and Pharmacy should collaborate on the following:
 - Build of the Anesthesia medication drug library
 - Periodic review of the anesthesia medication alert and alert response data
 - Maintenance and modification to drug library
 - Assessment of medication usage patterns when drug shortages occur
 - Review of appropriate preparation and dispense volume for controlled substances
 - Evaluate dispensed versus administered drug amounts for “right sizing” to prevent waste
- Ensure that standard concentrations and dosing units exist between the perioperative anesthesia and critical care areas

sion pump data records the exact amount of drug administered. The unused medication could potentially be diverted and must be accounted for as wasted. Controlled substance diversion monitoring can compare the dispensed volume with the administered and the wasted volumes to monitor for possible diversion. Minimizing opioid dispensing has been associated with a reduction in opioid-related complications in other patient care settings.^{17–19}

DRUG SHORTAGE

Drug shortages have unpredictable onsets and have become a national patient safety crisis. From 2010 to 2018, there were almost 1500 new shortages reported. Up to 63% of these shortages are related to injectable medications.²⁰ Drug shortages potentially force clinicians to use less familiar alternatives that may impact patient safety. Infusion pump data analysis might provide a more precise measurement of what drugs patients are being administered and amounts that are actually wasted which might aid in conserving the drug supply during a national shortage.

CONCLUSIONS

Smart infusion pump use has been shown to reduce patient harm from injectable medications, but safety features must be utilized to realize the full benefits of the technology. Health care organizations might seek additional ways to optimize use of this technology including the management of dispensed container volumes, opioid diversion, and drug shortage management. A multidisciplinary effort to build effective anesthesia drug libraries, standardize infusions, and engage in a process of ongoing data analysis will maximize the effectiveness of the devices and reduce the probability of medication errors.

Tim Vanderveen, PharmD, MS is a consultant to ICU Medical. He is a past member of the APSF Board of Directors and is a member of the APSF Committee on Technology. He was previously vice president, Center for Safety and Clinical Excellence for Becton Dickinson, and is a current shareholder.

Dr. O'Neill is the co-founder and chief clinical officer at Bainbridge Health. He is a current shareholder of Bainbridge Health.

Dr. Beard is medical director and shareholder of ICU Medical and a member of the APSF Editorial Board.

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Patient Blood Management Program Reduces Risks and Cost, While Improving Outcomes

by Tymoteusz J. Kajstura and Steven M. Frank, MD

The 2019 first-place Ellison C. Pierce, Jr., MD, Award for Best Abstract in Patient Safety was awarded to Kajstura and colleagues for their work entitled “Best Practice Advisories Increase Transfusion Guideline Compliance, Reduce Blood Utilization, and Save Cost.” In this review, they describe how the patient blood management program across the Johns Hopkins Health System has had positive impacts on patient safety, guideline compliance, and cost savings.

Within the Johns Hopkins Health System, a variety of approaches have been implemented under the patient blood management program which are summarized in Table 1.^{1,2} At the heart of the program is education, since over the past decade multiple landmark studies have been published supporting the concept that “less is more” when it comes to transfusion.³ In addition, transfusion guidelines were reinforced by best practice advisories (pop-up alerts) in the electronic order sets, to inform clinicians when orders were placed outside of guidelines.^{2,4}

These individual efforts have resulted in a large positive system-wide effect. Since the implementation of the patient blood management program, overall transfusion rates have decreased by 20% for red blood cells ($P = 0.0001$), 39% for plasma ($P = 0.0002$), and 16% for platelets ($P = 0.04$) (Figure 1).² Guideline compliance has increased, with 35% fewer out-of-guideline transfusion orders for red blood cells, 9% fewer for plasma, and 3% fewer for platelets. By reducing unnecessary transfusions, the hospital system has seen a significant cost savings;

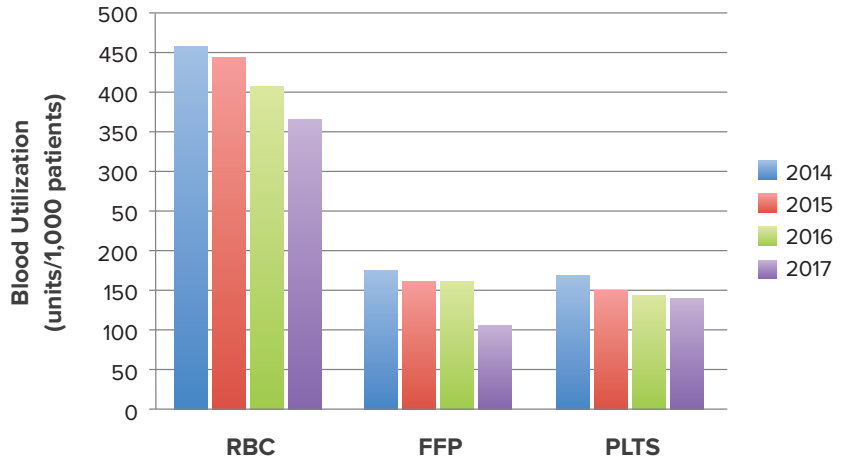


Figure 1: Across the entire health system, for each of the three blood components, changes in utilization (number of units per 1,000 patients) are shown over time. RBC—red blood cell, FFP—plasma, PLTS—platelets.

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comparing fiscal year 2017 (after most of these efforts were implemented) to 2014. There was an annual savings of \$2.4 million for the three blood products combined, representing a 400% return on investment for support of the program.² Most importantly, these changes are having a positive impact on patient safety with measures such as length of stay showing no change, morbidity/mortality decreasing from 1.5% to 0.75% ($P = 0.035$), and 30-day readmission rate decreasing from 9.0% to 5.8% ($P = 0.0002$).⁸ The success of this initiative at the Johns Hopkins Health System in patient blood management was in part predicated on the

diverse array of health care professionals and allies coming together with the common goal of optimizing the care of patients who may need transfusion.

Tymoteusz J. Kajstura is a medical student at Johns Hopkins University and Dr. Frank is professor in the Department of Anesthesiology and Critical Care Medicine and medical director of the Blood Management Program at The Johns Hopkins Health System.

The authors have no conflicts of interest.

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Table 1. Methods Used to Improve Blood Utilization Across the Health System

1. Obtain financial support from health system leadership.
2. Assemble a multidisciplinary team for monthly meetings.
3. Education: Grand rounds and on-line tutorials emphasizing evidence-based transfusion guidelines.
4. Harmonizing transfusion guidelines across the health system.
5. A “Why Give 2 When 1 Will Do?” single-unit red cell transfusion campaign. ⁵
6. Screen saver images reinforcing transfusion guidelines.
7. Clinical decision support with best practice advisories (best practice alerts, pop-up alerts). ¹
8. Data acquisition and analytics.
9. Transfusion guideline compliance audits with feedback (provider specific).
10. Minimizing iatrogenic blood loss (smaller phlebotomy tubes and less testing).
11. Anesthetic management: (normothermia, controlled hypotension, antifibrinolytics, acute normovolemic hemodilution). ⁶
12. Surgical methods: (minimally invasive approaches, newer electrocauterics, topical hemostatic agents).
13. Cell salvage. ⁷

APSF-Sponsored 2019 ASA Panel on "Practical Approaches to Improving Medication Safety"

by John W. Beard, MD, MBA; Eliot Grigg, MD; Joyce A. Wahr, MD; and Elizabeth Rebello, Rph, MD, FASA, CPPS

As a follow-up to the 2018 Medication Safety Stoeleting Conference, the APSF held a panel session titled "Practical Approaches to Improving Medication Safety" at the 2019 ASA Annual Meeting, in Orlando, FL. The goal of the APSF-sponsored safety panel was to provide front-line clinicians with actionable strategies to reduce medication errors.

Medication Safety Issues from a Manufacturer's Perspective

by John W. Beard, MD, MBA

Dr. Beard presented a view of medication safety through the lens of manufacturing safety and the anesthesia medication workflow. He identified key FDA safety principles, including the manufacturer's obligation to introduce products to market only after establishing that they are safe and effective for the intended use. He emphasized the importance of human factors engineering in medical device design and product testing. By citing recommendations from the European Union Medical Device Regulation, he stressed that risk is preferably eliminated through design, and when residual risk exists it should be mitigated through additional methods such as protective equipment, alarms, labeling, and training.¹

Computerized physician order entry, double-checked medication dispensing and preparation, and bar code medication administration at the time of administration for pills and injections may add a higher level of safety to medication administration practices. Adoption of smart pump-electronic health record (EHR) interoperability technology may also provide an improvement in medication safety. The interface between smart pumps and EHR works as a bidirectional wireless communication between the smart pump and EHR, which enables "auto-programming" of infusion parameters onto the pump and "auto-documentation" of infusion pump activity into the EHR. In non-OR environments, smart pump-EHR interoperability has been shown to reduce medication errors, increase efficiency, and increase the accuracy and completeness of documentation.²⁻⁴

Infusion pump medication errors in anesthesia were also highlighted. Although published data is limited, a 2010 New Zealand study demonstrated that nearly one-third of self-reported

medication errors were related to infusion pumps.⁵ In a 2018 University of Washington study, infusion pump errors were identified and significantly reduced by implementing a "smart pump bundle" which included implementing smart pumps for medication infusions, standardizing infusion concentrations, and using centralized pharmacy preparation of infusion medications.⁶

Dr. Beard recommended that anesthesia professionals take the following actions to improve infusion safety in the perioperative environment:

Table 1: Author's Suggestions To Improve Medication Infusion Safety

Utilize smart pumps for the delivery of medications and fluids*
Standardize smart pumps in operating rooms and nonprocedural locations
Standardize concentrations of continuous medication infusions for use in anesthesia and across units
Utilize centralized pharmacy preparation of continuous drips
Analyze smart pump data to evaluate clinician compliance and smart pump effectiveness

*This recommendation is consistent with draft ISMP smart pump guidelines, which indicate that fluids are preferentially administered by smart infusion pump although gravity administration continues to have application in select circumstances.⁷

Dr. Beard is medical director and shareholder of ICU Medical, Chicago, IL, and a member of the APSF Editorial Board.

Drug Administration Errors: Simple Steps to Improve the Anesthesia Workspace and Reduce the Risk of Medical Errors

by Dr. Eliot Grigg, MD

Dr. Grigg highlighted the importance of streamlining processes and simplifying options for medication handling in the OR.⁸ Many forms of safety countermeasures—like labels, alarms, and two-provider checklists—provide feedback instead of more robust constraints. Prefilled syringes, for example, eliminate 6 sub-steps (prescribe, prepare, dispense, administer, record, and monitor) and 19 possible failure modes from medication preparation versus bar-coding, which does not provide a physical countermeasure but does require user compliance.⁹ Ultimately, the goal of medication safety design is to eliminate unnecessary options (like excessive concentrations), automate processes (like wireless programming smart pumps), and

physically prevent mistakes (like new Luer connectors for regional anesthesia).¹⁰

Dr. Grigg is associate professor of Anesthesiology at University of Washington and has no financial disclosures.

Drug Shortages: Practical Substitutes When Your Most Important Anesthetic Medications are Missing

by Joyce A. Wahr, MD

Medication shortages have significantly impacted physicians in general and anesthesia professionals in particular, especially since the worst shortages involve sterile, generic medications. Shortages are inherently dangerous because providers must adapt to new and different appearances or formulations of standard medications, or become familiar with the dosing, side effects, and nuances of a substitute (e.g., glycopyrrolate for atropine).¹¹ When tracking shortages, the FDA only counts a medication in short supply when there is no other substitute available. The American Society of Hospital Pharmacists (ASHP), however, considers whether a shortage causes pharmacies to change how they provide that medication. Since an acute change in the look, concentration, or expiration date of a medication poses real risks for medication errors, the ASHP list of medications in short supply is more extensive than the FDA's shortage list.

The FDA has implemented a number of approaches to mitigate the impact of medication shortages but has little power to eliminate them.¹² Nearly 40% of injectables are produced by only one manufacturer, and any disruption in the supply chain or manufacturing may result in a shortage. Natural disasters, such as Hurricane Maria, which significantly impacted IV fluid manufacturing, can cause an abrupt reduction in the supply of medications. Consolidation of manufacturers, elimination of competition, changes in distributors—all make management of medication shortages extremely difficult.

Often hospital pharmacies have to reach outside normal distribution chains to maintain a normal supply of a critical drug. This process can lead to falsified or substandard medications, such as the substandard heparin that was responsible for at least 10 deaths in the US, or the chemotherapeutic agent that had no active ingredient.¹³ Medication shortages are expensive: most hospitals have a full-time pharmacist

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National Organizations Seek Solutions to Drug Concentration Standardization

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to manage shortages and shortages allow manufacturers to increase prices.¹⁴ Table 2 provides some clinical suggestions on how to approach drug shortages.

Dr. Wahr is a professor and vice chair of Quality and Safety in the Department of Anesthesiology, University of Minnesota. Dr. Wahr speaks on behalf of medication safety for Aspen Medical.

Standardization of Drug Labeling and Concentrations: Are We Different Than Other Groups Who Administer Drugs?

by Elizabeth Rebello, Rph, MD, FASA, CPPS

Standardizing drug concentrations may mitigate medication errors. This process should focus on developing the fewest number of drug concentrations to provide safe clinical care. Standardization may include a limited set of concentrations for medications that have been labeled as high-alert or are known to have produced a significant number of adverse events.

The ASA Committee on Quality Management and Departmental Administration (QMDA) convened a medication standardization safety workgroup to explore solutions regarding drug concentration standardization to safeguard patients with medication administration and to improve anesthesia professional workflow. An extensive literature review, closed claims studies, and the REMEDI database served as important sources of data for the workgroup.^{9,10,15-29} These efforts were highlighted in the 2018 Anesthesia Patient Safety Foundation (APSF) Stoelting Conference, “Perioperative Medication Safety²⁷: Advancing Best Practices,” and the following 10 medications were identified with recommendations for drug concentration standardization:

Insulin	Dexmedetomidine
Epinephrine	Hydromorphone
Norepinephrine	Lidocaine
Phenylephrine	Heparin
Ketamine	Remifentanyl

In addition to the lack of concentration standardization, drug mislabeling can increase patient risk. The APSF has created a standardization and innovation workgroup and has sponsored three conferences addressing overall medication safety. The Food and Drug Administration has made provisions for locations where specific types of labeling, such as the use of color-coded labels based on class of medication in the operating room, have an established use.¹⁶ The variance of medication administration in and out of the perioperative environment due to incremental versus complete administration further confounds the issue. Anesthesia professionals have a unique understanding of the challenges and should consider being engaged both at the local and national level to provide input regarding this important patient safety issue.

Dr. Rebello is associate professor in the Department of Anesthesiology and Perioperative Medicine at the University of Texas MD Anderson Cancer Center and has no financial disclosures.

CONCLUSION

The APSF has identified multiple techniques to improve medication safety in the operating room that are readily implemented in today’s procedural environment. Anesthesia professionals can adopt best practice medication safety techniques, including consideration of those summarized by the APSF Medical Safety Panel, to maximize patient safety and work to ensure that “no one shall be harmed by anesthesia care.”

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Table 2: Author’s Suggested Approach to Drug Shortages

Every anesthesia group should form a medication shortage committee that is led by pharmacists and includes cardiologists and intensivists
The committee should meet on a biweekly or monthly schedule to review developing and resolving shortages
Strategies for mitigation should be prepared, including waste reduction, use reduction, supplier change, substitute identification, or formulation changes
The committee should communicate shortage details to clinicians, including the mitigation strategies
Providers must also be alert to the possibility of substandard or falsified medications that may appear in our medication cart

A Difficult Airway Early Warning System in Patients at Risk for Emergency Intubation: A Pilot Study

by Stephen Estime, MD; Anna Budde, MD; and Avery Tung, MD

Management of a difficult airway during an out of operating room emergency intubation is associated with high morbidity and mortality.¹⁻⁵ Such patients are often unstable, and advanced airway equipment and skilled assistance are less available. Emergency airway management in the patient with an unanticipated difficult airway is particularly perilous when there is limited time to develop a plan or bring additional equipment to the bedside. Current literature suggests that difficult airway management is associated with a high incidence of desaturations, failed attempts, and difficult bag mask ventilation.^{1,3-5}

In principle, advanced knowledge that a patient has a difficult airway should reduce the risk of emergency intubation. In such patients, a plan can be formulated in advance, multidisciplinary expertise can be arranged, equipment can be made ready, and the decision to intubate can be made earlier to reduce time pressure. However, it is not cost-effective to assess the airway of every patient in the hospital (or even in the ICU) as only a small fraction of patients will require an emergency intubation.

To improve the quality of out of operating room difficult airway management, we partnered with our rapid response nursing team to incorporate airway assessments into the rapid response evaluation. Nurses were asked to identify known difficult airway patients based on medical history and by alerts such as bracelets and electronic chart alerts. The rapid response nurses were also taught to perform an abbreviated airway exam based on the Look, Evaluate, Mallampati Score, Obstruction and Neck Mobility (LEMON) score⁶ that could be utilized at the time of a rapid response evaluation to identify suspected difficult airway patients (Table 1).

Patients identified by the rapid response nurses as either known or suspected difficult airways were placed on a difficult airway "list" in the electronic medical record and their hospital course was monitored over a two-month period. We assessed for the incidence of emergency intubation and difficult intubation on post-intubation assessment. We defined a difficult airway as an intubation requiring more than two attempts of direct laryngoscopy by a senior anesthesia resident (PGY-3 and above) or attending and/or the use of adjunctive airway equipment (e.g., video laryngoscopy, fiberoptic bronchoscopy). Defining a difficult airway is variable,^{7,8} and we expanded the ASA's difficult airway definition⁹ of a conventionally trained anesthesia professional experiencing difficulty to include a senior resident because unlike operating room intubations, residents are often the first responders during an emergency intubation outside of the operat-



ing room and difficulties with initial attempts may quickly lead to patient morbidity. Documentation of a difficult airway is often subjective and inconsistent^{8,9} and by including the use of adjunctive airway equipment in our definition, we aimed for more objective criteria.

RESULTS

During the two-month pilot period, twenty-one patients were identified by rapid response nursing assessments as having a known or suspected difficult airway. Nearly 62% (13/21) required an emergency intubation during their hospitalization and 92% of those (12/13) had a difficult airway. Approximately 57% (12/21) of the known or suspected difficult airway patients were intubated emergently and had a confirmed difficult airway of which 58% (7/12) required video laryngoscopy and 42% (5/12) required fiberoptic bronchoscopy. None of the patients experienced failed airway management. One death occurred during a difficult intubation though this was in the midst of a cardiac arrest requiring chest compressions from a suspected pulmonary embolus prior to arrival of the emergency airway team.

Our data suggest that early warning of emergency intubation in known and suspected difficult airways is possible. Through strategic partnering, we created an early warning system which identified over half the patients who would require an emergency intubation and have a confirmed difficult airway. If formalized,

Table 1: Questions for identifying patients with a suspected difficult airway

- | |
|---|
| 1. Does the patient have limited neck range of motion (e.g., cervical collar, severe cervical neck disease)? |
| 2. Does the patient have limited mouth opening (e.g., connective tissue disorder, jaw wiring)? |
| 3. Does the patient grossly appear difficult (e.g., super morbid obesity, distorted facial anatomy, airway bleeding)? |

such an early warning system has considerable potential to improve the care of inpatients who require emergency intubation in the hospital. This pilot study was limited in its small sample size and short timeframe. Defining a difficult airway is highly variable as is the use of prophylactic video laryngoscopy and fiberoptic bronchoscopy during emergency intubations. Future work will focus on better identifying patients at high risk for emergency intubation. Ultimately, we plan to test whether advanced lead time changes how intubations are approached and whether these improve measurable patient safety outcomes.

Dr. Estime is an assistant professor of Anesthesia & Critical Care at the University of Chicago Medical Center.

Dr. Budde is an assistant professor of Anesthesiology at the University of Minnesota.

Dr. Tung is a professor of Anesthesia & Critical Care at the University of Chicago Medical Center. Dr. Tung also serves as the quality chief for the Department of Anesthesia and Critical Care at the University of Chicago.

Drs. Estime and Budde have no conflicts of interest to disclose. Dr. Tung serves as section editor for Critical Care & Resuscitation and Anesthesia & Analgesia.

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PRO-CON DEBATE

PRO: Artificial Intelligence (AI) in Health Care

by Michael Buist, MbChB, MD, FRACP, FCICM

This Pro-Con Debate took place at the 2019 Stoelting Conference entitled "Patient Deterioration: Early Recognition, Rapid Intervention, and the end of Failure to Rescue." The two following authors have expertise in the field of adopting artificial intelligence for managing patients who are deteriorating in the hospital setting.

Artificial intelligence (AI), or machine intelligence, has been defined as "intelligence demonstrated by machines, in contrast to the natural intelligence displayed by humans" and "...any device that perceives its environment and takes actions that maximize its chance of successfully achieving its goals."¹

Wikipedia goes on to classify AI into three different types of systems¹:

1. Analytical
2. Human-inspired, and
3. Humanized artificial intelligence

AI was founded as an academic field in 1956. Over the ensuing six decades, it has evolved to develop systems capable of undertaking complex real-time tasks that would be unachievable by the unassisted human brain. Early adopters in AI include the military, which has used autonomous and semi-autonomous drones; finance, in which AI enables real-time fraud detection; and the automotive industry, in which AI facilitates collision avoidance.

The multitrillion-dollar industry of health care has been slow to adopt information technology (IT) in general and AI in particular. This might be due to some of the conflicting interests that exist between the doctor/patient relationship and the documentation requirements of the health care profession, management and probatory requirements, and the existence of costly legacy IT systems.² While skepticism towards IT and AI solutions is understandable, our continued struggles with preventable adverse events,² poor adoption of evidence-based practice, and persistence in using non-beneficial, sometimes harmful practices³ argues for an earnest evaluation of the potential for AI to improve patient safety and outcomes.

The main argument for AI in health care is the potential to provide better real-time solutions for practitioners that improve outcomes for patients. One of the most important applications is the translation of research findings into consistent, reliable evidence-based practice occurring in the office and at the bedside. Admittedly, the development of "evidence" is fraught with inferential problems,⁴ but there are relatively uncontroversial evidence-based practices, such as avoidance of antibiotic prescribing for acute upper respiratory tract infections, where there remains a large evidence-to-practice gap.⁵ AI has the potential to, in real time, incorporate all patient data and outcomes relevant to a given clinical question. Such an AI system could prompt or alert practitioners when they are deviating from practice guidelines. Conceivably, AI could also continually update

and inform clinical practice guidelines using real-time patient data.

At its simplest, AI can be thought of as a decision rule: "what, if, then, and." For example, the "what" could be the patient with urosepsis, the "if" is the prescription of gentamicin, the "then" is renal function, and the "and" is what are the other prescribed medications. AI can then warn about drug interactions and provide precise and safe dosage information, which can then be altered in real-time based on variations in drug levels, other drug doses, and changes in renal function.⁶ This capability exists in most electronic prescribing systems. This author developed an AI approach in response to the problem of Rapid Response Team (RRT) "afferent limb failure" (e.g., not calling for help despite activation criteria being met).⁷ We identified several staff cultural problems that contributed to this phenomenon.⁸ The solution required electronic entry of patient's physiological observations, real-time comparison of those observations to the RRT activation criteria, and then issuing a series of automated alerts to the predetermined clinical team members. This system facilitated individualization of activation criteria for each patient as well as customization of the mode and order in which clinical team members are alerted. With this innovative approach, clinical response as per a National Health Service (NHS) Trust Hospital Early Warning Score (EWS) improved to 97% from a baseline of 68%.⁸

The argument for AI in health care is not about the potential for better reasoning and problem solving, knowledge presentation, natural language processing, and social intelligence; it is about doing the things in health care that, for whatever reason, we don't do, in part due to the frailties of the human brain. A compelling example is provided by Ruth Lollgen in the *New England Journal of Medicine*, writing about her personal experience of intimate partner violence.⁹ Despite being an emergency pediatric physician, she presents herself on numerous occasions to emergency departments with injuries that are consistent with a nonaccidental aetiology. Yet the pattern of the injuries on presentations and over time does not lead to any clinical suggestion of nonaccidental injury. She laments that no one asks the question of, "Do you feel safe at home?" Asking the important questions as above may provide improved safety for our patients and providers.

The complexities of health care, a rapidly growing body of research knowledge, an internet-savvy client and patient population, and, most importantly, the frailties of the human brain, necessitate the need for assis-



tance from AI to aid health care professionals in the day-to-day decision making about their patients. Health care professionals need to understand, and be involved in, the development of these machine-assisted decision devices so that they are constructed to the highest technical standards focused on best practice patient outcomes.

Dr. Buist is professor of Health Services at the University of Tasmania, Tasmania, Australia.

He is the founder, a previous director, and chief medical officer of Patienttrack. This company was sold to another health ICT company called Alcideon (ALC) that is listed on the Australian stock exchange. Professor Michael Buist is a substantial stockholder in ALC.

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CON: Artificial Intelligence is Not a Magic Pill

by Piyush Mathur, MD, FCCM

Artificial Intelligence (AI) is supposed to hold the promise of curing many problems facing health care such as predicting morbidity and mortality and outperforming physicians at diagnosis. In reality, despite increasing research, there are a limited number of clinically validated AI algorithms. Even as the number of U.S. Food and Drug Administration-approved AI applications grows, the implementation and widespread use of these applications has been challenging. Computer scientist Rodney Brooks described some of the challenges with AI predictions. These include overestimating or underestimating solutions, imagining magical algorithms, the scale of deployment, and performance limitations.^{1,2}

AI performance limitations are especially important in diagnostic AI solutions. Many researchers using artificial neural networks have claimed to improve diagnosis and outperform clinicians, as in diagnosis of diseases visualized on chest X-rays.³ Often, these self-limited, narrow spectrum algorithms can detect lesions such as atelectasis or infiltrates on chest X-rays. Despite claims of high accuracy however, these applications have been hard to replicate and generalize.⁴ In other approaches to machine learning, the computer algorithm learns from clinician-labeled data. In many publicly available chest X-ray data sets underpinning these algorithms, lesions are labelled by radiologists as infiltrates, mass, atelectasis, etc. These clinician assessments are considered the “gold standard,” but significant inter-rater differences have been noted,⁵ raising the specter of mislabeled datasets. Algorithms created from such mislabeled datasets are likely to have significant errors in their results which can confound clinician decision-making.

AI-based prediction of disease is similarly problematic. In the research done on prediction of acute kidney injury by Tomasev et al., prediction bias was introduced through the dataset itself. Their U.S. Veteran Affairs dataset contained only 6.4% female patients; model performance in these patients was lower than the rest.⁶ Bias continues to be a challenge even in administrative datasets and solutions developed for use by health care executives or insurance companies. As demonstrated by Obermeyer et al., these biases can be introduced at the level of algorithm development, but can also be based on the dataset used or the way the algorithm is implemented.⁷ These biased algorithms can lead to delivery of improper unsafe treatment to our patients.

Indeed, poor predictive values continue to limit the adoption of well-researched AI algorithms. Results based on the “area under the curve”—a statistical reflection of “model fit”—have been extensively exploited to report accuracy of these algorithms. However, multiple other parameters should be considered, including sensitivity and positive predictive value. Without good predictive values and replicable results, AI algorithms are unlikely to be adopted by clinicians.⁸

Scalability and generalizability of AI algorithms is another big challenge in health care. While electronic health records are the primary means to deploy many of these algorithms, poor interfaces, limited support for IT teams, and lack of integrated solutions still limit the ease of adoption.

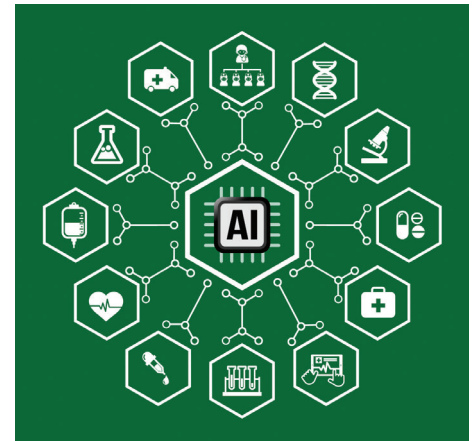
Marketing and hype created by some organizations has also had a negative impact and resulted in loss of credibility of AI amongst many clinicians. Some of the well-researched breakthroughs have been hyped enormously to leverage the current market value associated with AI. In a survey of European startups using AI by the London venture capital firm Marsh & McLennan Companies, Inc. (MMC), 40% were not actually using AI as a part of their product.⁹

AI does hold the promise of delivering potentially safer solutions for health care using the ever-increasing volume of data in an efficient and reproducible manner. But realizing this potential requires clinician leadership and rigorous clinical validation while developing and deploying AI algorithms (Table 1).

Table 1: Solutions for Effective Deployment of AI in Health Care

Patient- and care-provider-centric—first do no harm
Clinician leadership
Rigorous model development and testing
Explainable or Interpretable solutions—avoidance of black box
Clinical validation for generalizability and scalability
Cost-effective solutions

We are still in the early phases of research and development of AI algorithms for health care. Clearly, the growth in AI has been exponential and the pace is likely to continue in the near future. We need to be prepared to dedicate clinical, information technology, and financial resources to see effective utilization of these remarkable algorithms. Clinicians, espe-



cially radiologists and oncologists, are already leading the development of many AI algorithms to avoid ill-prepared solutions creeping into their work environment. Anesthesia professionals and perioperative clinicians who have been early adopters of technology and live in a data-rich environment also need to lead research, development, and deployment of sustainable AI algorithms to provide safer care to our patients.

Dr. Mathur is staff anesthesiologist/intensivist in the Department of General Anesthesiology and the quality improvement officer, Anesthesiology Institute, Cleveland Clinic, Cleveland, Ohio.

The author has no conflicts of interest to disclose.

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Balancing Sustainability and Infection Control: The Case for Reusable Laryngoscopes

by Diane Gordon, MD; Jodi D. Sherman, MD; Richard Beers, MD; and Harriet W. Hopf, MD

In their articles in the October issue of the *APSF Newsletter*, Drs. Prielipp, Birnbach, Schaffzin, Johnston, and Munoz-Price outline a comprehensive approach to infection control by anesthesia professionals.^{1,2} We agree with most of their recommendations, including frequent hand hygiene, cleaning the intravenous hub before injection, aseptic practices during medication preparation and administration, and decontaminating environmental surfaces.³ We respectfully disagree, however, with the authors' conclusion that single-use disposable (SUD) laryngoscopes are cost-effective compared to reusable laryngoscopes.

The authors' begin by calling for expanded reprocessing procedures for reusable laryngoscope handles. Implementing these expanded procedures would require disassembly and transport of the handles to a central reprocessing area. The authors go on to state that, "the cost of reprocessing reusable laryngoscopes to this new standard is substantial." As a result of their "new standard," the authors endorse "adopting single-use products [i.e., disposable laryngoscopes]" because they "may actually be quite cost favorable."^{1,2}

Requiring that laryngoscope handles undergo high-level disinfection is contrary to the recommendations of the Centers for Disease Control and Prevention (CDC) (<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html>)

While laryngoscope blades are properly required to undergo central reprocessing, we contend that the evidence does not support subjecting handles to the same standard. Laryngoscope handle contamination with primarily normal skin flora is well-documented.⁴⁻⁶ However, to our knowledge, there has not been a documented case of a hospital-associated infection transmitted by either laryngoscope handles or blades that were reprocessed as per current CDC guidelines.

We agree that laryngoscope handles should undergo a verifiable low-level disinfection process for surface decontamination just as any other environmental surface, and that blades should remain wrapped until their use on a patient.

Cost-benefit calculations must include assessment of environmental harms and medical waste costs. The World Health Organization (WHO) endorses this approach; in its World Health Report, WHO "strongly advocates the assessment of population-wide risks...in strategies for risk reduction." Each disposable laryn-

goscope handle contains lithium batteries, a light source, and metal and plastic that are rarely effectively recycled at present. Anesthesia professionals have a duty to consider the harm to global health associated with the manufacturing, packaging, transport, and disposal of these single-use items.⁷

In a recent comprehensive life-cycle analysis, a compelling case is made for reusable laryngoscopes on the basis of patient safety, environmental impact, and cost.⁴ When all costs were compared, reusable laryngoscopes were 10-fold less expensive than SUD laryngoscopes, and greenhouse gas emissions were 16–25 times less.^{4,8} Several studies suggest that disposable laryngoscopes have not been shown to provide superior reliability or intubating conditions compared with reusable laryngoscopes.^{4,8-9}

Without evidence of benefit, broad implementation of disposable laryngoscopes would substantially increase (and already has) anesthesia-related costs and pollution. Anesthesia professionals, as leaders in patient safety, have a duty to use evidence-based data to minimize the incidence and impact of adverse outcomes.^{9,10} In its broadest context, this includes adverse outcomes that impact public health.

Dr. Gordon is assistant professor of Anesthesiology at the University of Colorado and member of the ASA Environmental Task Force.

Dr. Sherman is associate professor of Anesthesiology, and of Epidemiology (Environmental Health Sciences), at the Yale School of Medicine, New Haven, CT, and member of the ASA Committee on Equipment and Facilities, and the Committee on Occupational Health and Safety. Dr. Sherman is also co-chair of the ASA Subcommittee on Environmental Health.

Dr. Beers is professor of Anesthesiology at the State University of New York, Upstate Medical Center and chair, ASA Committee on Occupational Health and Safety. Dr. Hopf is professor of Anesthesiology and adjunct professor of Biomedical Engineering at the University of Utah, Salt Lake City, UT, and a member of the ASA Committee on Equipment and Facilities.

Dr. Sherman has received a speaking honorarium from Getinge USA. Drs. Gordon and Beers have no disclosures.

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Introducing New Board of Directors Member Josh Lea



Josh Lea, DNP, MBA, CRNA

Josh Lea is a certified registered nurse anesthetist at Massachusetts General Hospital (MGH), Boston, MA, and serves on the faculty at Northeastern University's Nurse Anesthesia Program. His area of interest focuses on healthy work environments and most recently exploring proficiency among anesthesia professionals with advanced medical technology. Dr. Lea has presented on these topics nationally and internationally and is a member of MGH's CRNA Educational Committee and a past member of the AANA's Health and Wellness Committee. We are proud to welcome Josh as a new member of the APSF Board of Directors. He has also been a very active member of the APSF Editorial Board and as an APSF Social Media Ambassador.

RAPID Response

to questions from readers

Perils and Pitfalls With the Rapid Infusion Catheter (RIC)

by Eric McDaniel, MD; Roy Kiberenge, MD; Robert Gould, MD

INTRODUCTION

The rapid infusion catheter (RIC) is a device used to convert standard peripheral intravenous (PIV) access into a large-volume resuscitation portal.¹ The placement of this large-bore (8.5F) intravenous catheter is performed in clinical scenarios where clinicians anticipate the need for large volume resuscitation, and in our case, in preparation for a liver transplantation. This case illustrates once again how inexperience or unfamiliarity with invasive devices such as this “simple” intravenous catheter has the potential for perioperative complications and significant patient injury.

CASE DESCRIPTION

A 47-year-old man with past medical history of atrial fibrillation and hepatocellular carcinoma presented for a deceased donor liver transplant. After an uneventful induction of general anesthesia, we inserted an 8.5 French Rapid Infusion Catheter (RIC) (Figure 1) in anticipation of large-volume resuscitation. A standard technique was utilized for RIC insertion; i.e., a 20G peripheral intravenous (PIV) catheter was initially inserted in the right antecubital brachial vein, providing access for the RIC guidewire. The RIC vein dilator/8.5 F catheter assembly was then advanced to its normal position within the vein. To confirm venous placement, intravenous tubing was connected to the dilator hub to transduce vascular pressure and confirm venous placement. However, contrary to normal insertion procedures, the operator then failed to remove the venous dilator, and incorrectly attached one limb of the rapid infusion system tubing directly to the RIC dilator (Figure 2). The rapid infusion system ran smoothly, and high-pressure alarms were not triggered despite infusion rates up to 400 mL/min. Patient positioning was reconfirmed throughout the extended operation, and no swelling, edema, or signs of vascular extravasation were noted in the affected limb. It was only upon transport to the ICU the next day that the right arm was noted to be edematous secondary to an infiltration associated with the RIC dilator. The RIC system was removed, and the dilator was confirmed to have been left in place within the 8.5 F catheter itself.

DISCUSSION

The preloaded dilator-catheter assembly of the RIC system allows for efficient large bore peripheral venous access in patients. However, its pre-assembled dilator/catheter design led to a misunderstanding by the anesthesia professional in this case; thus, the entire assembly was incorrectly left *in vivo*. The Luer-lock connection to the vascular dilator was interpreted as “confirmation” of this (erroneous) assumption of where to connect the IV tubing. A subsequent root cause analysis (RCA) determined four contributing factors:

1. a lack of operator knowledge, skill, and experience with RIC insertion,
2. the supervising anesthesiologist was distracted by two concurrent invasive procedures,
3. the preloaded dilator on the RIC was devoid of any label warning it must be removed prior to transfusion, and
4. the ability to successfully connect intravenous tubing to the dilator itself.

We were fortunate that this event resulted in no permanent injury to the vascular system or soft tissue of the arm.² However this incident could have been catastrophic given that the system was attached to a high-volume, positive-pressure fluid infusion pump. Medical centers and departmental directors should ensure adequate education of all OR staff and anesthesia professionals whenever new or novel devices are introduced into the clinical arena.

Dr. McDaniel is a CA-2 anesthesiology resident at the University of Minnesota. Dr. Kiberenge is an assistant professor in the Department of Anesthesiology at the University of Minnesota. Dr. Gould is an associate professor in the Department of Anesthesiology at the University of Minnesota.

None of the authors have any conflicts of interest.

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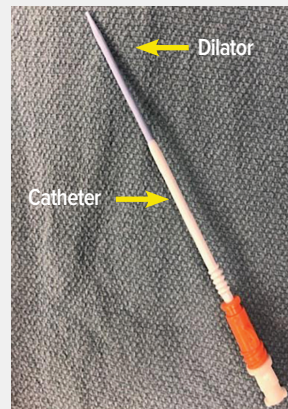


Figure 1: Depicts an 8 French Rapid Infusion Catheter with the dilator (blue) *in situ*.

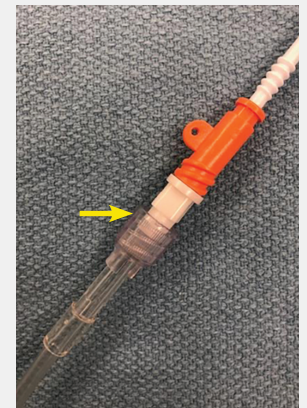


Figure 2: The yellow arrow shows the connection between the RIC dilator hub and infusion tubing.

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REPLY:

On behalf of Teleflex, I would like to thank you and the Anesthesia Patient Safety Foundation (APSF) for forwarding a letter, which you recently received from a physician describing an erroneous use of the Arrow® RIC® Rapid Infusion Catheter Exchange Set. The concern raised by the clinician was that the sheath/dilator assembly was left in the patient (without removing the dilator) and then connected to a rapid infusion system. This adverse event has been forwarded to the appropriate department within Teleflex and will go through the usual complaint management/risk evaluation process. In the meantime, we are committed to patient safety—as are you and the >122,000 anesthesia providers who will be receiving your publication—and we can only reinforce to clinicians the importance of using the device as instructed in the IFU.

Best regards,
Chris C. Davlantes, MD, FACEP
Medical Director
Vascular & Emergency Medicine
Global Clinical & Medical Affairs
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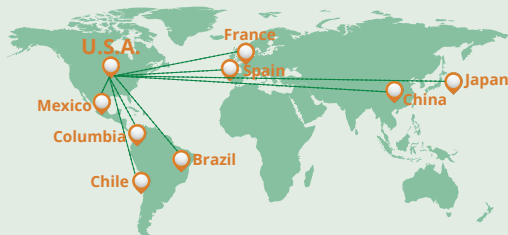
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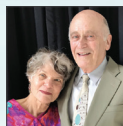
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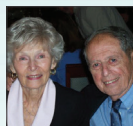
Mary Ellen and Mark Warner, MD



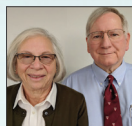
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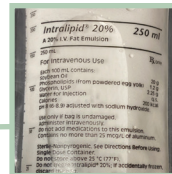


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