

NEWSLETTER

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Are Serious Anesthesia Risks of Semaglutide and Other GLP-1 Agonists Under-Recognized?

Case Reports of Retained Solid Gastric Contents in Patients Undergoing Anesthesia

by William Brian Beam, MD, and Lindsay R. Hunter Guevara, MD

INTRODUCTION

Glucagon-like peptide (GLP-1) receptor agonists are an emerging and increasingly popular class of medications used for the treatment of type 2 diabetes mellitus and, more recently, obesity. Since the expansion of approved uses to include weight loss, these medications have become increasingly popular. One mechanism of action of GLP-1 agonists is delayed gastric emptying.¹ We describe two cases of patients taking GLP-1 receptor agonists that were found to have high volumes of complex gastric contents despite appropriate fasting per American Society of Anesthesiologists (ASA) practice guidelines for preoperative fasting.² With the use of GLP-1 receptor agonists becoming increasingly more common, anesthesia professionals need to be aware of these



medications and the potential risks they pose to patients receiving anesthesia.

CASE 1

A 60-year-old female presented for magnetic resonance imaging with sedation for claustrophobia. She had a history of hypertension and was overweight (body mass index [BMI] 28 kg/m²). The month prior, she started *semaglutide* (*Ozempic, Novo Nordisk, Plainsboro, NJ*) for weight loss (last dose 7 days prior to presentation). Despite fasting from solid food for more than 18 hours prior to evaluation, she described feeling "full." A point-of-care gastric ultrasound was performed, which revealed solid gastric contents. The decision was made to cancel her imaging for fear of high risk of aspiration during the delivery of anesthesia.

CASE 2

A 50-year-old female with past medical history of class 2 obesity (BMI 37.7 kg/m²), type 2 diabetes, hypertension, and obstructive sleep apnea was scheduled to undergo a robotic-assisted hysterectomy for endometrial hyperplasia. Of note, she previously had gastroesophageal reflux disease, but these symptoms had resolved since she started *tirzepatide (Mounjaro, Eli Lilly, Indianapolis, IN)* 12.5 mg/0.5 mL pen injector injection (last dose 2 days before surgery).

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Consensus Recommendations for the Safe Conduct of Nonoperating Room Anesthesia:

A Meeting Report From the 2022 Stoelting Conference of the Anesthesia Patient Safety Foundation John Beard, MD; Emily Methangkool, MD, MPH; Shane Angus, CAA, MSA; Richard D. Urman, MD, MBA; and Daniel J. Cole, MD

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Nonoperating room anesthesia (NORA) cases are projected to exceed 50% of total anesthesia cases in the near future.¹ Although one large-scale study failed to show a difference in mortality between NORA and operating room (OR) settings,² multiple analyses of data from the American Society of Anesthesiologists (ASA) Closed Claims database have revealed

that adverse events occur nearly twice as often in NORA locations as they do in the OR.²⁻⁴

Patient safety in NORA locations may be compromised by problems with ergonomics, location, staffing, teamwork and communication, access to equipment, lack of adequate preoperative optimization, and much more. Other than the ASA Statement on Nonoperating Room Anesthetizing Locations, there have been no widely available recommendations on how to establish, maintain, and standardize safe workflows in NORA.⁵

In 2022, the Anesthesia Patient Safety Foundation (APSF) convened a multidisciplinary group of experts to organize the annual Stoelting Consensus Conference on "Crucial Patient Safety Issues in Office-Based and Non-operating Room Anesthesia."

GLOSSARY: APSF = Anesthesia Patient Safety Foundation; ASA = American Society of Anesthesiologists; NORA = nonoperating room anesthesia; OR = operating room

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Guide for Authors

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

The APSF Newsletter is the official journal of the Anesthesia Patient Safety Foundation. It is widely distributed to a variety of anesthesia professionals, perioperative providers, key industry representatives, and risk managers. Therefore, we strongly encourage publication of those articles that emphasize and include the multidisciplinary, multiprofessional approach to patient safety. It is published three times a year (February, June, and October). **Deadlines for each issue are as follows: 1) February Issue: November 10th, 2) June Issue: March 10th, 3) October Issue: July 10th.** The content of the *Newsletter* typically focuses on anesthesia-related perioperative patient safety. Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors.

- 1. All submissions should be emailed to <u>newsletter@apsf.org</u>.
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- Review articles, invited Pro/Con debates, and Editorials are original manuscripts. They should focus on patient safety issues and have appropriate referencing. The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.
- Q&A articles are submitted by readers regarding anesthesia patient safety questions to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.
- 3. Letters to the editor are welcome and should be limited to 500 words. Please include references when appropriate.
- 4. Rapid Response (to questions from readers), formerly known as, "Dear SIRS," which was the "Safety Information Response System," is a column that allows for expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Jeffrey Feldman, MD, current chair of the Committee on Technology, oversees the column and coordinates the readers' inquiries and the response from industry.

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GLP-1 Agonists and Aspiration Risk

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Her other medications included: metformin, hydrochlorothiazide, pregabalin, oxycodone, 5 mg as needed (intermittent use with last dose the day prior to surgery), and sertraline. She had been fasting since the night before surgery.

Anesthesia proceeded with an uneventful induction of general anesthesia and intubation. After intubation, an orogastric tube was placed and gastric contents (Figure 1) were suctioned.

The case was uncomplicated from a surgical perspective. At case completion, the patient was transferred to the transport cart and sat up in anticipation of emergence. Shortly before she was ready for extubation, she developed large volume emesis of particulate matter that was consistent with what she reported eating several days prior to surgery (Figure 2). Fortunately, the endotracheal tube was still in place and her airway remained protected. Once emesis was cleared, she was uneventfully extubated. She was closely observed in the PACU and did not have evidence to suggest gastropulmonary aspiration and was therefore discharged home later that day.

DISCUSSION

GLP-1 receptor agonists are an increasingly popular class of medications being prescribed to patients. These medications have been described as a "breakthrough" for weight loss. The GLP-1 receptor is expressed in a diverse range of organ systems including gastrointestinal (GI) tract, pancreas, heart, liver, and brain. Stimulation of this receptor leads to weight loss, improved glycemic control in diabetic patients, and improved cardiac and renal outcomes. The primary mechanism of action is related to both activation of vagal afferent nerves innervating the stomach as well as direct binding to GLP-1 receptors on gastric mucosal cells leading to delayed gastric emptying.¹ For diabetics, weight loss combined with stimulation of insulin secretion from pancreatic beta cells results in optimized hemoglobin A1c.³ Improvement in major acute cardiac events is likely related to both overall risk factor reduction (e.g., decreased glycated hemoglobin level, blood pressure control, decreased body mass index, decreased low density lipoprotein cholesterol level, improved glomerular filtration rate, and the decreased albumin-to-creatinine ratio) as well as via direct stimulation of GLP-1 receptors on myocardium leading to better endothelial function and microvascular perfusion.^{4,5} GI side effects like nausea, vomiting, or diarrhea are common, but symptoms may decrease with continued use.⁶ Acute pancreatitis as well as gallbladder and biliary disease, such as chole-

Table 1: Common GLP-1 Agonists.^{16,17}

	GLP-1 Agonists	Clinical Dosing	Pharmac HALF-LIFE	okinetics ELIMINATION	Special Considerations
1st Generation	Exanetide (Byetta®, Bydureon®)	SQ, twice daily (IR), weekly (ER), uptitrated	3 hours	Renal	Associated with immune-mediated thrombocytopenia
1st Ge	Lixisenatide (Adlyxin®)	SQ, daily, uptitrated	3 hours	Renal	No longer available in United States
2nd Generation	Semaglutide (Wegovy®, Ozempic®) (Rybelsis®)	SQ, weekly, uptitrated Oral, daily, uptitrated	7 days	Renal	Approved (SQ formulation only) for weight loss
	Liraglutide (Saxenda®, Victoza®)	SQ, daily uptitrated	12.5 hours	Renal	Approved for weight loss
Ā	Dulaglutide (Trulicity®)	SQ, weekly	4.5 days	Renal	
	GLP-1/GIP Agonist				
	Tirzepatide (Mounjaro®)	SQ, weekly	5 days	Renal	Approved for weight loss

SQ = Subcutaneous.



Figure 1: Depicts gastric contents in a patient on a GLP-1 agonist, who appropriately adhered to ASA fasting guidelines.

cystitis, have also been described. Although rare, anaphylactic and angioedema reactions have been described.⁷

Despite the benefits of the class of medications on obese and diabetic patients, there are potential anesthetic risks. GLP-1 receptor agonists have a known mechanism of action of slowed gastric emptying.⁸ The medications may lead to high volumes of complex gastric contents despite appropriate fasting per ASA practice guidelines for preoperative fasting. Both patients presented in this case series were taking a GLP-1 receptor agonist (Table 1) to treat diabetes and assist with weight loss. And, although pulmonary aspiration is a rare complication in patients undergoing anesthetic care, it is devastating. In addition, it is among the top three adverse events related to airway management in the ASA closed claims project.⁹ The most common etiology of aspiration is related to passive or active regurgitation of gastric



Figure 2 : Depicts large volume emesis of particulate matter in a patient on a GLP-1 agonist that was consistent with what the patient reported eating several days prior to surgery.

contents.^{10,11} For this reason, recognition of patient populations at elevated risk for increased gastric volume is key to delivering a safe anesthetic (Table 2).

Although it was avoided in these cases, the risk for pulmonary aspiration in sedated or anesthetized patients with unprotected airways is concerning. In the first case, close attention to the patient's history and symptoms, combined with assessment with gastric ultrasound, led to case cancellation and avoidance of a high-risk situation for the patient. In the second case, the patient was noted to have a high volume of complex intragastric contents with orogastric tube placement and emesis of solid gastric contents at the time of emergence consisting of food from 2–3 days before surgery. It is unclear if the GLP-1 receptor agonist was

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Guidance for Perioperative Care in Patients on GLP-1 Agonists

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the direct cause of the high volume of remaining gastric contents as the patient also had long-standing diabetes and was using opioids, both associated with gastroparesis.^{12,13} As evidence of our concern about patients taking GLP-1 receptor agonists, we identified a recent case report that described a patient taking semaglutide who experienced an aspiration event with food remains during induction of anesthesia despite having fasted for 18 hours.¹⁴ Furthermore, we found several retrospective reviews of patients taking GLP-1 receptor agonists undergoing endoscopy that showed an increased risk of retained gastric contents in patients on these medications.^{15,16}

The ASA's Task Force on Preoperative Fasting recently released a consensus-based guidance on preoperative management of patients on GLP-1 receptor agonists (Figure 3).¹⁷ For elective procedures, the expert group's recommendation is to withhold daily dosed GLP-1 receptor agonists the day of the procedure and weeklydosed formulations a week prior. On the day of the procedure, the recommendation is to ask specifically about GI symptoms, such as nausea, vomiting, abdominal pain, and abdominal distension, and consider delaying elective procedures in patients who are symptomatic. If patients are asymptomatic from a GI standpoint and medications were held per guidance, their recommendation is to proceed with the procedure. In patients without GI symptoms, but who have not held the medication as advised, the task force recommends proceeding with "full stomach" precautions with consideration for evaluating gastric volume by ultrasound to aid in decision-making. This group noted there is no evidence to suggest optimal duration of fasting.¹⁷ Other professional organizations such as the Society of Perioperative Assessment and Quality Improvement have also put forward consensus recommendations to hold GLP-1 receptor agonists on the day of surgery unless there is heightened concern for postoperative gut dysfunction.¹⁸ Given the long half-life of most medications within this class, stopping medications for at least 5 half-lives before surgery to allow normalization of gastric function is not feasible. Further, given the potential cardiovascular benefits and negligible risk for hypoglycemia, there is interest in continuing this class of medications without perioperative interruption.¹⁹

At this point, the optimal approach to these patients still needs to be refined and hopefully additional studies will help guide our decision-

Table 2: Risk Factors for Aspiration.

High risk for ileus/bowel dysmotility
Acute pancreatitis
 Recent intra-abdominal surgery
Inpatient receiving opioids/prolonged bedrest
Emergency Case
Case with prolonged duration or complexity
Active GI Bleed

• Asai. T. Editorial II: Who is at increased risk of pulmonaary aspiration? Br J Anaesth. 2004;93:497-500.

Robinson M, Davidson, A. Aspiration under anaesthesia: risk assessment and decision-making. Continuing Education in Anaesthesia, Critical Care & Pain. 2014;14:171–175.

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Figure 3: American Society of Anesthesiologists Consensus-Based Guidance on Preoperative GLP-1 Receptor Agonists Management*

ASSESSMENT:

Given concerns regarding reports of delayed gastric emptying related to GLP-1 receptor agonists, the ASA Task Force on Preoperative Fasting released guidance regarding preoperative management of these medications.

For patients scheduled for elective procedures consider the following:

DAY(S) PRIOR TO THE PROCEDURE:

- Irrespective of indication (diabetes or weight loss), for patients on weekly dosing consider holding GLP-1 agonists a week prior to the procedure/surgery. For patients on daily dosing consider holding GLP-1 agonists on the day of the procedure/surgery.
- If GLP-1 agonists prescribed for diabetes management are held for longer than the dosing schedule, consider consulting an endocrinologist for bridging the antidiabetic therapy to avoid hyperglycemia.

DAY OF THE PROCEDURE:

- If GI symptoms such as severe nausea/vomiting/retching, abdominal bloating, or abdominal pain are present, consider delaying elective procedure, and discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.
- If the patient has no GI symptoms, and the GLP-1 agonists have been held as advised, proceed as usual.
- If the patient has no GI symptoms, but the GLP-1 agonists were not held as advised, proceed with "full stomach" precautions or consider evaluating gastric volume by ultrasound, if possible, and if proficient with the technique. If the stomach is empty, proceed as usual. If the stomach is full or if gastric ultrasound is inconclusive or not possible, consider delaying the procedure or treat the patient as "full stomach" and manage accordingly. Discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.
- There is no evidence to suggest the optimal duration of fasting for patients on GLP-1 agonists. Therefore, until we have adequate evidence, we suggest following the current ASA fasting guidelines.

*Excerpted from American Society of Anesthesiologists Consensus-Based Guidance on Preoperative Management of Patients (Adults and Children) on Glucagon-like Peptide-1 (GLP-1) Receptor Agonists. <u>https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/american-society-of-anesthesiologists-consensusbased-guidance-on-preoperative</u>. Updated June 29, 2023. American Society of Anesthesiologists.

making. A systematic approach to assessing risk in this patient population with a careful history of medication use, symptoms, and review of comorbidities is important. It may be prudent to re-evaluate traditional fasting guidelines in these patients. The use of gastric ultrasound to define

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Further Research Required to Quantify Aspiration Risk Perioperatively in Patients Taking GLP-1 Agonists

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gastric contents prior to anesthesia can be considered in patients presenting for anesthesia on these medications, when available.²⁰⁻²² In the setting of uncertainty regarding gastric contents, rapid sequence induction of anesthesia and gastric decompression prior to emergence could be considered. It should also be recognized that the risk for emesis and aspiration during emergence is also a real concern even with gastric decompression if the patient has residual solid gastric contents.

CONCLUSION

We present two cases of patients on GLP-1 receptor agonists with delayed gastric emptying despite appropriate preoperative fasting. We acknowledge it is difficult to ascertain the direct cause of the delayed gastric emptying in these patients as there were numerous risk factors. Nevertheless, with the use of GLP-1 receptor agonists becoming increasingly common, anesthesia professionals need to be aware of these medications and the potential risks they pose to patients receiving anesthesia. Further studies investigating the safety of these agents as it relates to the management surrounding the peri-anesthetic period are needed.

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The authors have no conflicts of interest.

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NORA Consensus Recommendations (cont'd)

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The objective of the conference was to determine consensus recommendations for best practices in NORA around areas of facility and location, equipment and supplies, staffing and teamwork, patient selection, periprocedural care, and quality improvement. A brief summary of our process and results follows.

METHODS

The conference planning committee (the authors) created a conference program to address the unique challenges of NORA (Table 1). Simultaneously, they created the first draft of NORA recommendations, which was then revised and sent to conference speakers and attendees. The recommendations were revised consistent with the feedback provided and presented to breakout groups during the conference. Additional feedback and revisions were then presented to all conference attendees on the last day for discussion and voting. After the meeting, there were further revisions from the conference planning committee, speakers, and participants, which led to consensus-derived recommendations (Supplemental Digital Content 1, Table 1, http://links.lww.com/AA/E369). Ethical considerations, inclusion and exclusion criteria, a list of speakers, and further details of the consensus development process can be found in Supplemental Digital Content 2, Appendix A, http://links.lww.com/AA/E370.

RESULTS

A summary of the 42 recommendations is presented in Supplemental Digital Content 1, Table 1, http://links.lww.com/AA/E369. These recommendations apply to the provision of anesthesia or sedation in NORA locations. which include, but are not limited to, non-OR procedural areas in the inpatient and outpatient settings, including office-based areas like dentistry. These recommendations related to the following domains: facility (9 statements), equipment, medications, and supplies (16 statements), staff and teamwork (4 statements), preprocedure care and patient selection (6 statements), intraprocedure care (2 statements), postprocedure care (3 statements), and continuous quality improvement (2 statements).

DISCUSSION

NORA locations are known to be fraught with patient safety concerns and high stress.^{6,7} The ASA's Statement on Nonoperating Room Anesthesia provides guidance on safety considerations for NORA related primarily to facility and equipment issues. The APSF recommendations build on these considerations and provide a template for clinicians to improve teamwork,

Table 1: 2022 Stoelting Conference Session Description.

Day	Session	Objectives		
1	Requirements for a safe and effective anesthetic regardless of location	Understand the issues that may lead to mismatch between patient selection and preparation and the capabilities of NORA locations and their staff		
1 Appropriate patients and procedures		Review patient selection criteria, appropriate staffing, equipment, and monitoring availability to deliver anesthesia appropriate to the situation and any other issues associated with potential patient safety problems in isolated procedure rooms, free-standing surgical centers, offices, and procedure centers		
1	Designing NORA for patient safety: beyond current state to a future best practice	Discuss opportunities to promote patient safety using clear outcome measurements and data-driven improvement initiatives in all NORA cases		
2	Impending issues: disruptors and innovation	Craft specific recommendations that APSF can use to influence changes that improve patient safety in NORA practices		

Abbreviations: APSF, Anesthesia Patient Safety Foundation; NORA, nonoperating room anesthesia.

personnel, and preoperative optimization, which are key patient safety issues in NORA.^{1,5}

The recommendations address many areas that are cited as contributory to safety problems in NORA: facility and location, access to equipment and supplies, teamwork issues, periprocedural care, and quality improvement. While the need for anesthesia services outside of the OR has expanded exponentially in the past decade,^{8,9} few hospitals are constructed with NORA as a priority. Accordingly, anesthesiology departments have had to retrofit what they need for safe anesthetic care into spaces designed for other purposes. NORA locations may be on different floors than the main OR, or even in different buildings, impeding rapid access to additional personnel and equipment in case of emergency. These consensus recommendations establish clear expectations for the facility, including grouping of procedural areas close to one another and the main OR when possible, establishment of scavenging capabilities and adequate oxygen supply, and need for sufficient electrical outlets and lighting to facilitate safe care.

Many NORA locations do not have sufficient equipment to provide safe anesthetic care, which may contribute to patient safety events.^{2,10} These recommendations provide standards for facilities to provide emergency airway equipment and capability for rescuing malignant hyperthermia and local anesthetic toxicity, if applicable. The consensus recommendations also provide guidelines for clinician safety; many areas lead clinicians to perform procedures under fluoroscopy. In fact, the anesthesia provider may have radiation exposure equivalent to the proceduralist, and thus, sufficient protection from radiation is required.¹¹

In many procedural suites, the proceduralist and nursing team may not be as familiar with working with anesthesia teams. This lack of familiarity may lead to unfavorable team dynamics and the lack of "belonging," which can impede patient safety.7 Lack of familiarity both among team members, and with anesthetic procedures and concerns—as well as poor communication, can lead to adverse events in NORA.^{1,2,12-14} While the physical space, ergonomics, and location of NORA areas may be more difficult to alter, human factors-related interventions may be easier to implement. Improvements in teamwork and communication are imperative to improving patient safety in these areas and can be facilitated by team training, smaller, more dedicated teams, and shared knowledge about complex cases.

There can be significant production pressure in NORA that can lead to shortcuts. The consensus recommendations advocate for thorough preoperative workup as well as standardized communication before the procedure begins (e.g., formal timeout). Periprocedural monitoring should occur according to standards established by the ASA.^{15,16} The recommendations also acknowledge the need for both anesthesia and procedural services to review cases for quality of care, with focus on continuous quality improvement.

There have been other recommendations for how to improve anesthetic care in NORA. Notably, Herman et al¹ published a recent narrative review of safety issues in NORA and used an engineering framework to provide recommendations for improvement. The recommendations presented here differ as they originate

NORA Consensus Recommendations (cont'd)

From "NORA Consensus," Preceding Page

Supplemental Table 1: Consensus summary for the safe conduct of anesthetic care in NORA locations.

FACILITY

- Anesthesiology personnel should participate in planning, construction, expansion, or remodeling of NORA locations to ensure that patient safety and anesthetic needs are met.
- 2. Anesthesiology personnel should encourage facility design teams to group NORA suites together, near the OR, or the PACU, to facilitate rapid access to additional personnel and equipment when needed.
- A reliable source of oxygen adequate for the length of the procedure and an immediately available backup supply are required. A central oxygen supply is ideal.
- 4. A scavenging or capture system for anesthetic gas is required in locations where inhaled anesthesia is used.
- Electrical outlets shall be sufficient to supply anesthesia equipment and labeled to identify the backup power supply. The number of outlets available for backup power shall be sufficient to power equipment required to safely care for patients.
- 6. Lighting shall be available to visualize the patient, equipment, supplies, and medications. Battery-powered backup lighting shall be available.
- 7. There should be sufficient space to accommodate personnel with adequate clearance and expeditious access to the patient, equipment, supplies, and medications. Sufficient space shall be available to bring emergency equipment into the room.
- 8. A source of continuous suction shall be available and dedicated for use by anesthesiology personnel.
- 9. Pre- and postprocedural areas shall be available for preparing and recovering the patient.

EQUIPMENT, MEDICATIONS, AND SUPPLIES

- 1. Anesthesiology personnel should participate in capital budget planning for equipment required to set up, maintain, and improve NORA services.
- 2. When volatile anesthetics are administered, an anesthesia machine sufficient for case types and maintained to facility standards is required.
- Emergency airway equipment, including multiple forms of rescue (e.g., supraglottic airways, video laryngoscope, cricothyrotomy kit, etc.) is required for each NORA location.
- 4. A self-inflating hand resuscitator bag capable of delivering positive pressure ventilation while administering at least 90 percent oxygen is required.
- In each NORA location, emergency supplies including a defibrillator, medications, and other equipment to provide cardiopulmonary resuscitation are required.
- 6. Equipment and medication for treatment of MH shall be present in all locations where volatile anesthetics are used.
- Succinylcholine or other equivalent rapid acting paralytic medications should be immediately available for emergency airway management in all NORA locations. When succinylcholine is present, staff shall be educated on MH and prepared to provide and aid treatment.
- 8. Infusion pumps should incorporate dose error reduction systems (DERS).
- Diagnostic testing capability appropriate for the patient population and planned procedures is required.
- Appropriate blood products and the equipment required for administration, such as a fluid warmer, shall be available for procedures that may have clinically significant blood loss.
- MRI-safe equipment, including airway equipment, infusion pumps, monitors, and anesthesia machines shall be available for MRI, and providers trained on their use. Patient monitoring consistent with operating room standards should be displayed in the MRI control room.
- 12. Intralipid for treatment of local anesthetic systemic toxicity (LAST) shall be available at NORA locations where local anesthetic is used for purposes other than local skin infiltration.
- Patient size and weight capacity limits should be established for each NORA site to confirm patient suitability based on equipment and other available resources.
- 14. Crisis manuals appropriate for the patient population, procedures, and potential therapeutic complications shall be available to staff and clearly visible in each NORA location to serve as cognitive aids during emergencies.
- 15. Protective equipment, including, but not limited to lead aprons, goggles and radiation shields shall be made available to all anesthesia personnel where radiation exposure may occur.
- 16. Equipment, such as inflatable mattresses, for patient transfer to and from procedure table shall be available to avoid injury to patient and personnel.

- STAFF AND TEAMWORK
- 1. Communication, team building, expectations, and training should be established through a proactive collaborative process driven by anesthesiology personnel, nursing, surgical, and proceduralist leadership.
- In each NORA location adequate staff shall be trained to support the patient and the anesthesiology care team. The NORA team shall include at least two individuals with appropriate certification (ACLS, BLS, or PALS) and defined responsibilities to provide patient care during emergencies.
- Anesthesiology personnel should triage and evaluate complex cases, assist with scheduling, and optimize quality and safety protocols. A dedicated NORA anesthesiology team should be considered to facilitate communication and the adoption of protocols and pathways.
- 4. Team members names and roles should be posted in the NORA location to facilitate communication during patient care.

PREPROCEDURAL CARE AND PATIENT SELECTION

- A preprocedural evaluation process shall be established based on the ASA Practice Advisory for Preanesthesia Evaluation and emerging best practice.
- 2. Adult and pediatric patient comorbidities should be identified which require specialized preoperative evaluation or necessitate procedural care in an inpatient facility.
- 3. Adult and pediatric patients with elevated BMI or a diagnosis or suspected diagnosis of OSA should be evaluated on a case-by-case basis for suitability for the planned procedural location and management plan.
- 4. Before each procedure, a timeout shall be conducted per The Joint Commission Universal Protocol or according to the facility protocol including site marking and laterality as indicated.
- Appropriate education shall be provided to team members for new or unfamiliar procedure types, and specific aspects of the case shall be reviewed with NORA staff.
- 6. All patients should be assessed for fall and venous thromboembolism risk and treated appropriately.

INTRAPROCEDURE CARE

- Intra-procedural monitoring shall adhere to ASA Standards for Basic Anethetic Monitoring with additional monitoring based on patient comorbidities and/or the nature of the procedure.
- A formal system to call for assistance, designate personnel to respond, and transport a patient with appropriate monitoring from the NORA location to an in-patient facility shall be established.

POSTPROCEDURE CARE

- 1. Appropriate postanesthesia management shall be provided per ASA Standards for Postanesthesia Care.
- 2. Recovery and discharge guidelines shall enable patient assessment in a simple, clear, and reproducible manner.
- Patients who receive medications for sedation or anesthesia (but not local anesthetics alone) shall be discharged with a responsible individual who can ensure the safe transport of the patient to their home.

CONTINUOUS QUALITY IMPROVEMENT

- Anesthesia personnel should establish a quality review process to identify possible new safety risks and improve care on a regular basis.
- Periodic emergency response simulations should be performed to review system, communication, equipment, and educational infrastructure.

NORA, non-operating room anesthesia; OR, operating room; PACU, postanesthesia care unit; MH, malignant hyperthermia; MRI, magnetic resonance imaging; ACLS, advanced cardiovascular life support; BLS, basic life support; PALS, pediatric advanced life support; BMI, body mass index; OSA, obstructive sleep apnea; ASA, American Society of Anesthesiologists

Recommendations Generated From Multidisciplinary Cohort of Health Care Professionals and Experts

From "NORA Consensus," Preceding Page

from a multidisciplinary cohort of clinicians and health care representatives with extensive expertise in NORA, who, through an iterative process, have provided consensus statements on approaches for the safe conduct of anesthesia in NORA locations. Indeed, these consensus recommendations supplement existing literature and should be used in concert with previous work.

While most general principles were agreed on by the vast majority of conference attendees and experts, the scope of the recommendations generated the greatest amount of discussion and passion during the development process. There was extensive discussion regarding whether to narrow the scope of the recommendations to inpatient only, or if there should be separate recommendations for ambulatory and office-based anesthesia. This is likely a reflection of the diversity of NORA practice, including inpatient, ambulatory, and office practices. In particular, the example of patient harm in pediatric dental cases generated significant discussion.¹⁷ Indeed, patient morbidity and procedural complexity in inpatient locations differ significantly from complexity in outpatient and office-based locations, and there was extensive discussion about whether facility and personnel requirements for inpatient NORA should be required in outpatient or office-based NORA. Some requirements may not be possible—for example, having separate preanesthetic and postanesthetic care areas. The consensus recommendations are the "bare minimum" for safe patient care in NORA and are intended to apply to all NORA locations. Many common patient safety elements apply across the entire NORA population, and the final recommendations were endorsed by clinicians working in inpatient, ambulatory, and office-based NORA.

These recommendations provide a starting point for dedicated anesthesia teams in NORA to improve patient safety, but do not provide strategies for implementation, as these may be



specific to both the individual facility and the hospital system. There were several other limitations in the process used to develop the recommendations. First, the content and focus of the conference itself may not fully capture all essential considerations during NORA practice. Second, the final draft of recommendations is dependent on the first draft, which was created by a small group of experts, each of whom may have biases regarding NORA best practices. Third, the planning committee members and speakers were predominantly from academic practices, which may bias the content of the recommendations themselves. Fourth, although nonanesthesiology specialties were represented, they were individual specialists and may not be representative of their entire specialties. Fifth, the conference attendees selfselected for the conference and may not be representative of the general medical community. Finally, while significant effort was put forth to create an inclusive and psychologically safe environment for all participants, it is possible that group discussions may have led to suppression of contrary viewpoints and unexpressed opposition or support. The multiround survey and recommendations review process enabled anonymity to other participants; however, the breakout, discussion, and voting sessions of the conference were likely influenced by the public nature of the discourse and understandable reluctance from participants to share opinions openly.

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In summary, these recommendations represent another step toward improving patient safety for NORA patients. They are intended to facilitate the reengineering of health care systems in the best interests of the patient so that medical errors are designed out of the NORA component of the system. NORA cases will continue to comprise an ever-increasing portion of anesthetic practice, and clinicians must continue to remain advocates for patient safety.

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to questions from readers

Electronic Interference Between the Blink Twitchview[™] and Medtronic Situate[™] Detection System X

by Jerome Lax, MD

Recently at our institution, toward the end of a laparotomy, a puzzling event occurred. As a radiofrequency detection wand (Medtronic Situate[™] Detection System X, New Haven, CT) was waved over the abdomen, an electronic interference alert was triggered. Subsequent assessment of the operating room environment revealed that the source of this interference was the Twitchview[™] train of four monitoring device (Blink[®] Device Company, Seattle, WA). We ascertained that the Medtronic detection system display will read "SCAN OBSTRUC-TION" if the wand is positioned within 4 feet of Twitchview[™]. We also discovered that this interference is eliminated by disconnecting the Twitchview[™] device from its AC power source. This is achieved either by unplugging its power cord from the wall socket or removing the device from its cradle. While the actions mentioned above may be a temporary fix to this issue, we have approached both manufacturers with an eye toward implementing a more definitive technological solution to this incompatibility.

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Jerome Lax, MD, has no conflicts of interest.

Blink Device Company Response: Electronic Interference Between the Blink Twitchview[™] and Medtronic Situate[™] Detection System X

Dear APSF Rapid Response,

We would like to thank Dr. Lax and the APSF for bringing this issue to our attention. For readers who may not be familiar with these devices, the TwitchView® train of four monitor is used throughout the surgery like other vital signs monitoring equipment, while the Situate™ device is typically used at the conclusion of surgery to ensure that surgical sponges have not been left behind. The TwitchView monitor uses a Qi-certified wireless battery charging system. Qi is a wireless charging standard developed by the Wireless Power Consortium that operates between 110–205 kHz and is used in the iPhone and many other commercial wireless charging systems. The Medtronic Situate[™] System device uses Low Frequency RFID which operates in this same frequency band. We were able to confirm that the "SCAN OBSTRUC-TION" on the Situate was caused by the Twitch-View[®] wireless charging system and replicated the same "SCAN OBSTRUCTION" message using a wireless iPhone charger. Of note, the TwitchView System continues to function normally in the presence of the Situate device.

We confirm that the approach described by Jerome Lax, MD, (unplugging TwitchView or unseating the TwitchView monitor from the charging base to pause the wireless charging) during a Situate scan will eliminate the interference and still enable functional use of the Twitchview (TwitchView can operate on battery power). Blink is investigating alternate Qi-certified charging systems in an effort to find one that is less prone to trigger a "SCAN OBSTRUCTION" on the Situate device and is collaborating with Medtronic to identify additional solutions. Given the increasing use of wireless battery charging systems, we encourage our industry partners to consider the potential for device interaction when designing devices that operate in these frequency bands.

Justin Hulvershorn, MD, PhD CEO Blink Device Company

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NORA Consensus (cont'd)

From "NORA Consensus," Preceding Page

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LETTER TO THE EDITOR: **A Preventable Airway Management Disaster**

There has been tremendous growth and progress in airway management in the past four decades, despite an increase in high-risk groups such as patients of extreme size and weight, trauma, and obstructive sleep apnea, to name a few.¹ The introduction and refinement and widespread adoption of airway management guidelines, coupled with technological advances such as the introduction and widespread use of newer supraglottic airways, indirect laryngoscopes (video laryngoscopes), advances in invasive airway emergency methods, advanced methods of peri-intubation oxygenation methods such as noninvasive positive pressure ventilation, and high-flow nasal oxygenation, have revolutionized how we approach the airway in elective and emergency settings.² Airway management procedures are required in patients of all demographics and are performed by health care providers with different experience and training backgrounds. While the trends seem promising, significant adverse events still occur, and we must not let our guard down.

A recent international consensus guideline sheds light on an old airway management adverse event.³ The members of the Project for Universal Management of Airways (PUMA) came out with Management Guidelines for preventing unrecognized or undetected esophageal intubation. These new guidelines were endorsed by seven airway management societies from across the world.³ Some readers might be taken aback. Is there a need for such guidelines in the 21st century? Chances are that every practitioner has experienced firsthand, during laryngoscopy and intubation, a case in which the endotracheal tube (ETT) accidentally ends up in the esophagus. If this happens and it is immediately recognized, little harm comes out of misplaced ETTs. The real problem comes when the ETT is misplaced, there is delayed recognition, or it is missed altogether. This may result in severe, irreversible hypoxic brain damage or even death.⁴⁻⁶

The exact rate of unrecognized esophageal intubation is unknown. Incidences as high as 4-26% of all intubations have been reported in high-risk groups such as trauma, low-flow states, and neonates.^{5,7,8} While it is estimated that more cases occur outside the operating room and when the procedure is carried out by nonanesthesia personnel, anesthesia professionals are not immune to unrecognized esophageal intubations. The incidence of by Felipe Urdaneta, MD, FASA

engaged in airway management and it is

underreported.14-17



follow strict protocols to reduce the incidence of esophageal intubation altogether. Using videolaryngoscopy as a first-choice device seems prudent and backed up by literature.¹⁶ However, this is currently not universally possible and remains aspirational due to perceived cost and limited resources even in affluent countries. Ensuring correct tracheal tube placement after every intubation and continuous monitoring of exhaled CO₂ in patients with mechanical ventilation should always be performed. Not all instances of esophageal intubation happen during intubation; endotracheal tubes might be dislodged from the respiratory tract. This is especially common in the pediatric population or when the patient's head or body moves altogether, for example, during resuscitation maneuvers. A high index of suspicion of esophageal intubation should be present if it is impossible to ventilate a patient on a mechanical ventilator. This becomes evident after administration of neuromuscular agents. There are many anecdotal reports of patients with misplaced ETTs who can breathe so long as their diaphragmatic function is preserved; once this

Esophageal intubation can happen even in the hands of experienced health care professionals.

See "Preventing Airway Disaster," Next Page

Preventing Unrecognized Esophageal Intubation is Paramount to Patient Safety

From "Preventing Airway Disasters," Preceding Page

It is not just a problem for inexperienced or less skilled providers. It may not always be possible to prevent esophageal intubations. The goal should be to prioritize and work on measures to help prompt the detection of tracheal tube placement. These new guidelines remind us to resist being complacent and passive in promoting measures to decrease undue patient harm.

In conclusion, these newly published Guidelines on preventing unrecognized esophageal intubation shed a modern view on an old problem, a low-frequency, high-impact adverse event. Despite many technological advances and successes, there is still a lot to be learned. No patient should be harmed by unrecognized esophageal intubation, and we should all abide by the fundamentals to reduce this unwanted event.

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Steven B. Greenberg, MD APSF Newsletter Editor; Secretary, APSF; Clinical Professor, Department of Anesthesia and Critical Care, University of Chicago

to questions from readers

Recurrent Intraoperative Anesthesia Machine Malfunctions

by David W. Corpman, MD, and Linda L. Liu, MD

Intraoperative equipment failures are increasingly rare events, but may cause serious harm based on an analysis of the American Society of Anesthesiologists (ASA) Closed Claims database.¹ Pre-anesthesia checkout procedures strive to make these events preventable, but certain failures cannot be prevented with a standard checklist. A task force organized under the ASA Committee on Equipment and Facilities initiated a comprehensive anesthesia apparatus checkout recommendation which we follow at our institution.² Despite this practice, our institution recently experienced two critical malfunctions of the General Electric Aisys Anesthesia Carestation (GE Healthcare, Chicago, IL).

Both instances resulted in power loss to the anesthesia monitor display unit leading to the loss of all ventilation parameters, cessation of mechanical ventilation, and the inability to use volatile anesthetics. During both cases, the cause of the anesthesia machine malfunction was not immediately known, but both intraoperative teams eventually identified a loose connection behind the anesthesia monitor display unit (Figure 1). One case identified a missing securement screw where the System Power Interface cable (Cable A) is connected to the display unit. For the second case, the cables appeared connected, but an untightened screw was discovered upon closer examination. After firmly reinserting the Cable A into the back of the monitor, the anesthesia machine progressed through the startup cycle. The anesthesia monitor display unit then displayed a nonspecific error screen ("internal problem prevents normal operation") and instructed the user to mechanically ventilate with the alternate O₂ control and cycle power on the anesthesia machine (Figure 2). Alternate O₂ control was automatically engaged shortly after the malfunction occurred, and both cases briefly utilized total intravenous anesthesia because the power failure precluded use of volatile anesthetic agents. After the machine restarted, both anesthesia teams were able to resume normal operations, and there was no patient harm.

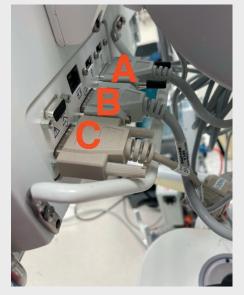


Figure 1: Cable A: System Power Interface; Cable B: System Signal Interface; Cable C: Serial Port – standard interface for external communication to electronic health record.

Upon review of the error history after the events, the logs noted two errors: "DU to PSC Comm Error" and "POWER CNTRL COM FAIL," pointing to a disconnection of the communication cable between the anesthesia controller board and the anesthesia monitor display unit (Figure 3). Recreating this error with a biomedical technician demonstrated that even a slightly untightened screw can lead to a transient cable disconnection with movement of the monitor arm. The machine will not initiate the startup sequence until the communication cable is reseated firmly. A similar error has also occurred with cable "C" disconnections (Figure 1), which interrupt anesthesia machine external communication to the electronic health record.

Our anesthesia machines are fifteen years old and nearing fleet replacement. On the 12-month preventative maintenance (PM) schedule, checking these communication cables is listed under "Visual Inspection Procedure".³ These loose connections are also not detected by the automated machine check or standard preinduction checklists. These cases



Figure 2: Error screen instructing the user to mechanically ventilate with the alternate O_2 control and cycle power on the anesthesia machine



Figure 3: Error log showing "DU to PSC Comm Error" and "POWER CNTRL COM FAIL"

are the first occurrences of this malfunction at our institution, but we are concerned that this will happen with increasing frequency with other anesthesia machines in our fleet as the screws continue to disengage over time.

A solution to this fault would be placement of a retainment clip as a redundant securement mechanism. Redundancy to prevent failure of critical systems is a hallmark of safety innovation not only in anesthesia, but also in aviation and other industries.⁴⁻⁵ Improved designs can prevent errors particularly for rare problems where standard checklists may fail.⁶ Unfortunately, this proposal may not be feasible given

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the current design and the number of machines in clinical service. After fifteen years of use, older anesthesia machines are probably experiencing more screw failures along with other maintenance requirements. The General Electric Aisys Anesthesia Carestation would not meet ASA anesthesia machine obsolescence guidelines for several more years.⁷ We have asked our biomedical department to retighten the screws for all our anesthesia machines and suggested a more proactive PM requirement to confirm that these screws are tightened to prevent cable disconnections. Heightened vigilance about this potentially catastrophic vulnerability is necessary as these machines age.

Preventing Cable Disconnections on the Anesthesia Machine

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The authors have no conflicts of interest.

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GE HealthCare Response: Recurrent Intraoperative Anesthesia Machine Malfunctions

Dear APSF Rapid Response,

GE HealthCare would like to thank the team from University of California San Francisco School of Medicine for submitting their experience with an Aisys Anesthesia Machine display cable disconnection resulting in loss of the display and control during two procedures. In response to this report, GE HealthCare performed an extensive review of the technical description of the failure, the design of the display cable, and GE HealthCare's servicing documentation (Technical Reference Manual).

Per the description in the report, the cable that became disconnected is the communication cable between the Display Unit and the Anesthesia Control Board. When there is a communication loss between the Display Unit CPU and the Anesthesia Control Board CPU, the system is designed to display the "System Malfunction" screen as described in the report.

The report points out that the loose cable connection is not detected by the pre-use machine checkout and/or during preventative maintenance. As this condition is a result of a communication loss between the Display Unit CPU and the Anesthesia Control Board CPU, the machine will enter the System Malfunction state if the communication loss is greater than 10 seconds regardless of the state of the machine (Power-up, Checkout, or Planned Maintenance). Therefore, if the disconnect were to have occurred, or been present, during pre-use machine checkout it would have been identified.

The Maintenance Procedures section in the Technical Reference Manual recommends a visual inspection procedure of the machine including a step to "Check all external electrical cabling. Ensure all are correctly connected and are not deteriorated." This portion of the Maintenance Procedure is intended for the service personnel to check the condition and tightness of the external cables, including the display communication cable.

Also, the recommended maintenance for the Aisys Anesthesia Machine, as detailed in the Maintenance Procedures section, requires the 3v battery in the display CPU to be replaced every 48-months. The replacement of this battery requires the display cables to be disconnected and the display to be removed from the Aisys Anesthesia Machine. Therefore, it is likely based on the age of the machines that these display cables have been removed and reinstalled at least three times since the machine was manufactured.

GE HealthCare strives for continuous improvement and will consider the authors' suggestions for maintenance improvements and cable retention for future designs.

www.gehealthcare.com/about/contact-us

Sincerely, Anthony Bean Systems Engineering Manager – Anesthesia & Respiratory Care GE HealthCare



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Remimazolam: Patient Safety Considerations of a Novel, Practice-Changing Drug in Perioperative Medicine

by Arnoley S. Abcejo, MD, and Miguel T. Teixeira, MD

INTRODUCTION

Remimazolam besylate (ByFavo[™] in the USA and in South Korea, Anerem[®] in Japan, Aptimyda[™] in EU, and Ruima[®] in China) is an intravenous, short-acting, and ultrafast onset benzodiazepine (nonanalgesic) with potent sedative-hypnotic, anxiolytic, anticonvulsant, and muscle relaxant properties. As its name suggests, the makers of the drug have attempted to combine the familiarity and therapeutic effects of midazolam with the unique metabolism of remifentanil.

So far, remimazolam has found a clinically impactful role in procedural sedation in Asia and Europe since its release in China in 2019 for use in gastrointestinal endoscopy. In Japan and Korea, its use has now been approved for general anesthesia, and, in Belgium, remimazolam was used for ICU sedation.^{1,2} In the United States, the FDA approved remimazolam for induction and maintenance of sedation in adults undergoing procedures lasting 30 minutes or less in July 2020³ with non-FDAapproved uses being reported extensively in the literature. Despite this, few centers have acquired the drug, formulated internal guidelines for its use, and applied it to a large clinical practice.

As of publication of this article, our institution, the Mayo Clinic, is one of the first major academic centers in the United States to widely adopt remimazolam into the perioperative and periprocedural practice. We have used it in over 5,000 patients with over 20,000 doses administered. We are in the process of investigating definite clinical areas where remimazolam has an important practice-changing role including possibilities for safe clinical expansion.

In this review, we combine the available literature with our institutional experience on remimazolam's patient safety profile amongst various clinical practices. We specifically discuss the unique pharmacokinetics and pharmacodynamics of remimazolam and outline some important nuances about its known limitations. adverse advents, and contraindication for use. We summarize key clinical practice implications and elucidate important knowledge gaps for its safe, widespread adoption including its role in anesthesia as well as nurse-driven sedation. We conclude with lessons learned regarding what is known and unknown about remimazolam's meaningful clinical outcomes, effects on practice efficiency, and patient safety profile.

 Table 1: Quick Reference Guide for pharmacology and dosing for remimazolam.

REMIMAZOLAM ByfavoTM(U.S.)

Class: Benzodiazepine

Sedation Time: 11-14 minutes Time of peak effect: 3-3.5 min (1x); 11-14 min mult.doses) Half-life elimination: 37-53 min

Metabolism Esterase-dependent

Excretion

via urine

Distribution (V_D) 0.76 to 0.98 L/kg

Protein-Binding >91%, primarily to albumin

Dosing Regimen

FDA-Label Recommendation

2.5-5 mg bolus over 1 min

Supplemental doses 1.25-2.5 mg over 15 sec after 2 min.

*Summarized from Teixeira et al. The Role of Remimazolam in Neurosurgery and in Patients With Neurological Diseases: A Narrative Review. J Neurosurg Anesthesiol. May 31 2023

Abbreviations: FDA = Food and Drug Administration (U.S.), min = minutes, multi = multiple, mg = milligram, sec = seconds.

PHARMACOLOGY: A BRIEF REVIEW

Remimazolam's mechanism of action is comparable to other benzodiazepines in that it enhances the gamma-aminobutyric acid type A (GABA_A) inhibitory receptor leading to increased frequency of opening of ligand-gated chloride ion channels. It has desirable pharmacodynamics and exhibits minimal cardiac or respiratory depression. It has faster onset and dose dependent sedation than midazolam⁴ and is approximately half as potent⁵ for procedural sedation (Table 1). Like other benzodiazepines, its sedative effects can be reversed using flumazenil which have comparable active durations of effect.

From a pharmacokinetic standpoint, remimazolam has relatively high clearance, a small steady-state volume of distribution, shorter elimination half-life, and a short context sensitive half time compared to other benzodiazepines or propofol.⁶ Remimazolam is highly bound to protein and extensively metabolized primarily by liver carboxylesterase being excreted primarily in the urine.⁷⁸ As such its structural modifications are similar to remifentanil in that it is a faster onset, titratable shorteracting benzodiazepine.⁷

Remimazolam is water-soluble and when diluted into a solution becomes a painless injectate. It is most soluble in slightly acidic environments and can precipitate in lactated or acetated Ringers solution (Figure 1).^{9,10} It is compatible with y-site co-administration of common anesthetic drugs including remifentanil, fentanyl, dexmedetomidine, midazolam, and common neuromuscular blockers such as rocuronium and vecuronium.¹¹ Currently, ByFavo® remimazolam is prepared in a 20 mg powder vial which is meant to be drawn up into 8.2 mL sterile 0.9% sodium chloride, making it 2.5 mg/ml after being reconstituted. The FDA labeling recommends 2.5–5 mg push injection over a one-minute time period followed by supplemental doses of two 1.25–2.5 mg aliquots intravenously over a 15-second time period after at least two minutes.³ In our experience, for procedural sedation, we typically dose 2 mg IV every 15 seconds as needed with or without

Remimazolam and Patient Safety

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analgesic adjuncts including ketamine or opiates (Figure 2). For induction of general anesthesia, we have employed a 0.2–0.4 mg/kg induction dose followed by 1–2 mg/kg/hr (Figure 2).¹² Remimazolam has very low bioavailability (<2%).⁸

UNKNOWN PATIENT SAFETY CONSIDERATIONS FOR REMIMAZOLAM

Remimazolam appears to be a relatively safe medication. However, we likely do not fully understand the impact of remimazolam on clinical outcomes after specific surgeries or procedures or within specific patient populations. Given its relative novelty and limited clinical use thus far, we advise continued caution recognizing that much remains unknown. <u>Reporting</u> <u>unexpected serious adverse events is encouraged</u>. Some patient safety considerations or questions that should be elucidated are as follows:

- · Recovery in neurologically vulnerable patients: Most common benzodiazepines are considered to promote the development of delirium. Therefore, they should be administered with caution in neurologically vulnerable patients, particularly in the elderly. Current studies describing postoperative delirium after remimazolam are limited and likely not generalizable to larger populations or procedure types. Furthermore, the relationship between remimazolam administration and long-term postoperative neurocognitive disorder has not been established. We have described the most recent literature on remimazolam in a recent JNA 2023 review article (Figure 2).^{13,14}
- · Adverse reactions in specific patient populations and surgical subtypes: The pharmacokinetic properties of remimazolam appear to not be significantly altered in elderly or those patients with higher ASA scores.¹⁵ We follow the FDA recommendations for slight dose reduction and will also reduce the dose in those with severe hepatic impairment (Child-Pugh score \geq 10) as they appear to have reduced drug clearance.¹⁶ No dose adjustments are needed for those with renal disease.¹⁶ Currently there is no pediatric labeling for general anesthesia or sedation, but off-label case reports of its use, predominately as an adjunct to general anesthesia, have been summarized in the literature.¹⁷ We have not found any reported cases of its use in pregnant patients.
- Administration and practice guided by nonanesthesia professionals: Midazolam is a

 REVENUE
 Remimazolam (ByfavoTM) 20 mg in 10 mL Plasmalyte

 Image: Contract of the state of the

Figure 1: Photograph of 20 mg remimazolam (ByFavo") drawn into 12 mL syringe of 10 mL plasmalyte. Yellow arrows highlight precipitate formation.

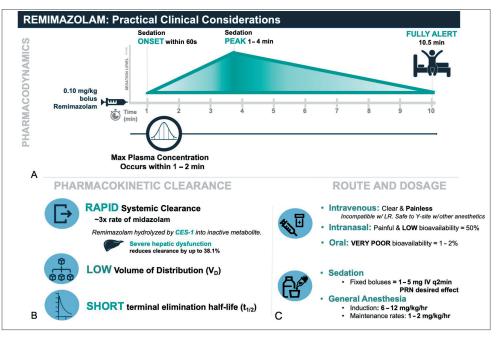


Figure 2: Remimazolam pharmacokinetic and pharmacokinetic profile adapted with permission from Figure 2 from Teixeira et al. "The role of remimazolam in neurosurgery and in patients with neurological diseases: a narrative review." J Neurosurg Anesthesiol, May 31, 2023.

Abbreviations: mg = milligram, kg = kilogram, hr = hour.

commonly administered drug by periprocedural nursing staff. While gastrointestinal endoscopic studies have described safe use of remimazolam by nonanesthesia professionals, we have found adapting to primaryremimazolam from a primary-midazolam sedative nursing practice can take significant time, training, and cultural shifts.

 Cost and Access: Currently, remimazolam is invariably more expensive than more common sedative medications like midazolam and propofol. However, faster recovery times may facilitate increased procedural throughput and counter increased costs.^{5,18}

ADVERSE REACTIONS AND CONTRAINDICATIONS

Overall, remimazolam appears to be a safe anesthetic drug as its adverse reactions tend to be mild, short-lived, and reversible by a single dose of flumazenil. Despite its relatively short

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context-sensitive half-life, care must be taken to ensure adequate reversal in those with prolonged infusions, patients with significant liver disease, and congruent opioid administration. Resedation from remimazolam after reversal with flumazenil is unlikely but has been reported.¹⁹

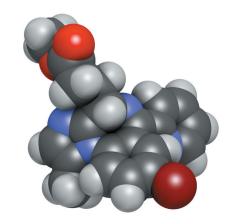
Common adverse reactions include blood pressure and heart rate variations, body movement, nausea, dizziness, and headaches.^{2,3} To put these into context, when compared to propofol, these risks have been reported as less likely, but similar to midazolam use.^{20,21} Importantly, remimazolam when co-administered with other central nervous system depressants including opioids, may lead to synergistic effects and may lead to significant respiratory depression. Also, anaphylaxis is possible and has been reported.²² The use of remimazolam is specifically contraindicated in patients with known severe hypersensitivity reactions to Dextran 40.³

There are early conflicting and limited data regarding remimazolam and its potential link to postoperative nausea and vomiting. It likely leads to a reduction in the incidence of postoperative nausea and vomiting when compared to volatile anesthesia alone,²³ but not when compared to propofol.²⁰

CLINICAL PRACTICE IMPLICATIONS

Anecdotally, at our institution, remimazolam has quickly found a significant role in almost every area of practice—particularly in clinical areas with more clinically complex patients and procedures. Here are specific clinical areas where remimazolam has found a significant role in our practice and within the medical literature:

- Complex Cardiovascular or Hemodynamically Unstable Patients: Remimazolam has limited impact on respiratory depression, systemic vascular tone, and inotropic, dromotropic, or chronotropic function. Therefore, many anesthesia professionals in our practice use it in the cardiac catheterization lab (routinely for cardioversions) and during cardiac surgery and trauma cases in patients with limited cardiopulmonary reserve.²⁴
- Non-Operating Room Anesthesia (NORA)
 - Gl and Pulmonary Endoscopic Procedures: Some of the largest body of literature for remimazolam exists in endoscopy at this time. These trials have shown comparable efficacy for procedural sedation with a safety profile notable for fewer effects on hemodynamic function, a lack of pain with



Remimazolam

intravenous administration, reduction of postprocedure nausea and vomiting, and a rapid return to baseline neurologic function. ^{22,25,26}

- Interventional Radiology: Patients requiring sedation under anesthesia care for interventional radiology often carry complex comorbidities, require deeper levels of sedation, or are too unstable for open surgical management. Moreover, these procedures often have limited, intermittent periods of discomfort. Remimazolam may have a significant role in providing sedation, amnesia, and anxiolysis during these procedures.
- Magnetic Resonance Imaging (MRI): Some patients require anesthesia support for MRI due to a variety of reasons, (e.g., claustrophobia, musculoskeletal discomfort, tremors, etc.) Remimazolam, in some patients, has been a uniquely valuable tool for MRI sedation. Anesthesia professionals have also used dexmedetomidine in conjunction with remimazolam for monitored anesthesia care in the MRI environment.²⁷ In some patients with back pain, specifically central spinal cord stenosis, we are concerned that supine positioning under anesthesia could lead to prolonged or permanent spinal cord ischemia. Intermittent remimazolam boluses for sedation have allowed us to achieve a level of sedation adequate for accurate scans while at the same time, permitting intermittent neurologic exams. Small doses can provide enough patient anxiolysis while maintaining a patent airway to complete a brain MRI. At the time this article was written, we do not formally have nurses performing sedation with remimazolam.
- Neurosurgical Procedures: We recently reviewed our institution's use of remima-

zolam in neurosurgery¹⁴ including its known effects on neuromonitoring and processed EEG. Particularly advantageous in neurosurgery, the pharmacokinetics and pharmacodynamics of remimazolam allow for rapid amnestic sedation and anxiolysis followed closely by a rapid meaningful neurologic exam. As such, we have used remimazolam for the following procedures: awake craniotomies for periods of discomfort during pin placement, local anesthetic administration, urethral catheter placement, and surgical incision.

LOOKING AHEAD: REMIMAZOLAM' S IMPACT ON PERIOPERATIVE PATIENT SAFETY

In the two years of clinical experience with remimazolam, we have seen rapid expansion of its clinical use. This is likely attributed to its attractive pharmacokinetics, relative respiratory and hemodynamic safety profile, and its ability to be rapidly reversed. We predict this trend will continue as we expand its use to nurse sedation practice, especially within outpatient and ambulatory settings. Anesthesia professionals have a unique opportunity to identify patient safety practice guidelines, clinical guardrails, and safety algorithms for remimazolam. More large patient cohort safety data are forthcoming to truly delineate its safety profile compared to the other commonly used sedatives in the anesthesia professionals' arsenal.

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Clinician Safety in NORA

by Candace Chang, MD, MPH; Jens Tan, MD; Patricia Fogarty Mack, MD; and Diana Anca, MD

INTRODUCTION

While patient safety is an established field of study, little attention has been directed to clinician safety. According to the Occupational Health Safety Network, 1 in 5 nonfatal occupational injuries occurs in the health care and social assistance industry, and health care workers experience seven times the national rate of musculoskeletal disorders.¹ The most frequently documented causes of injury were patient transport and "slips, trips, and falls."¹

Occupational hazards of working in nonoperating room anesthesia (NORA) locations, such as interventional radiology suites, electrophysiology and catheterization labs, endoscopy suites, and magnetic resonance imaging suites, have not been studied. Musculoskeletal pain is more common in health care workers working in interventional laboratories and is highest among nonphysician employees.² This article highlights key occupational hazards anesthesia professionals face in NORA locations and provides suggestions to create a safer working environment.

ROOM SET-UP

Many NORA suites are retrofitted and have insufficient floor area to comfortably accommodate anesthesia machines, automated medication dispensers, and other equipment. Cramped and nonstandard positioning of anesthesia equipment may make clinician movements to access the patient, airway, and injection ports awkward and nonergonomic. The dimmed ambient lighting necessary for fluoroscopic imaging and lack of pathway lighting increases the risk of tripping or sustaining a concussion from a head strike on radiology screens or booms.

Procedures may require the proceduralist and anesthesia professional to change locations often, depending on imaging modality and anatomic site being treated. The anesthesia machine and the drug dispensing system may need to be moved frequently from one side of the room to the other, which poses two specific hazards to anesthesia professionals.

First, anesthesia machines can weigh between 100 and 165 kilograms. While the machines are on wheels, persons moving them need to pay attention to proper body mechanics as well as the presence of cords or other floor obstacles obstructing the wheels. The undue physical strain may be multiplied when different physical layouts increase the frequency of anesthesia machine movement.

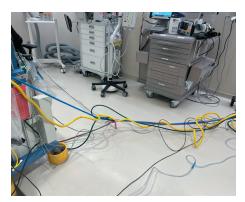


Figure 1. Gas lines, data cable, power cord, suction tubing from anesthesia machine causing trip hazard.



Figure 3: Commercial mat covering hoses.

The second hazard that arises from variable placement of the anesthesia machine is from the associated cables, hoses, and lines. Anesthesia machines will have at least three hoses (oxygen, air, and scavenger waste gas) and a power cord. Additional connections can include a vacuum hose for suction, nitrous oxide, computer cords, and data cables (Figure 1). At MD Anderson, at least two anesthesia professionals in the last ten years reported falling after tripping over such cables (Figure 2). There are various solutions to mitigate the risk of falls, including commercially available cable "sleeves" and specially designed mats (Figure 3). These have their own challenges, however, such as the potential for increased bacterial contamination and the mat itself slipping on procedure room floors. One strategy is to place "anti-fatigue" mats over the cables, but this solution relies on having conscientious team members place them at the beginning of every case. Another mitigation strategy is to braid the gas lines (Figure 4). The best solution would be to design procedure rooms with gas and electrical outlets arising from mobile overhead booms so that gas lines can be stored behind the anesthesia machine (Figure 5).



Figure 2: Anesthesia provider injuries to face after tripping over exposed cables. Permission to use from provider granted.



Figure 4: Braiding gas lines mitigates the trip hazard.



Figure 5: Gas outlets on a mobile boom attached to the ceiling.

NORA Clinician Safety

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ROOM DESIGN

Anesthesia professionals need to be involved in the design, planning, and construction of new procedure suites. A well-designed room for patient care decreases both floor trip hazards and hanging obstacles like gas lines or electrical cords. This reduces physical strain on clinicians as they reach for needed equipment for patient care.

The proper placement of anesthesia equipment should be prioritized, with related placement of gas lines, suction, electrical outlets, and internet ports. Adequate space needs to be allotted for anesthesia equipment in the correct configuration to the right of the patient's head (at least for induction and emergence) and for the clinician to have unimpeded access to the patient.³ The ASA Statement on NORA Locations states, "There should be in each location, sufficient space to accommodate necessary equipment and personnel and to allow expeditious access to the patient, anesthesia machine (when present), and monitoring equipment."³ Weill Cornell Medicine's Department of Anesthesiology has designated that the minimum space for anesthesia services planned in all new procedure or operating room designs should be 12 feet by 7 feet. This 84-square-foot area should be reserved for the anesthesia machine, medication and equipment cart, IV pole, and chair as a minimum to ensure the anesthesia professional's ability to safely move around the workspace.⁴ Many imaging suites are designed solely to accommodate the large imaging equipment and moving patients in and out of the room, with little attention paid to workflow for the technologists, nurses, advanced practice providers, and physicians who care for the patient. Space for patient beds and accessibility for easy transfer of both mobile and immobile patients should be ensured.

Based on the authors' experience, whenever possible, patients should enter on the side of the room opposite from the anesthesia machine, gas lines, and cords. Rooms should have two doors to allow for easy access of equipment and personnel for regular workflow and in case of emergency. In rooms with only one door, the anesthesia professional and patient's head should be closest to the door so that personnel arriving to help in an emergency can immediately assist. Gas lines should be piped in close to and behind the anesthesia machine with a dedicated line for waste anesthesia gas disposal (WAGD). The National Fire Protection Agency (NFPA) states that any location where nitrous oxide or halogenated anes-



thetic gas is intended to be administered should have a WAGD inlet.⁵ While NFPA guidelines are not legally binding, this is a consensus standard referenced by the Joint Commission.⁶

In addition to the procedure room, anesthesia professionals should advocate for appropriate preprocedure and postprocedure recovery locations close to the procedure room, and have an expeditious pathway for patient transfer to the intensive care unit. Too often not enough space or thought is given to these important aspects of patient care that can significantly impact safety and efficiency.

PATIENT TRANSFERS

Patient transfers can be particularly awkward in NORA locations due to cramped workspace and lack of equipment to assist in patient transfers, since these areas may have been designed for nonanesthetized patients to move themselves. There are several patient repositioning systems, such as AirTap (Prevalon AirTap, Sage Stryker, Cary, IL) or HoverMatt (HoverTech International, Allentown, PA), designed to help transfer patients who cannot move themselves. While they were designed to enhance patient safety, they also improve clinician safety by limiting musculoskeletal strain.⁷

INVISIBLE HAZARDS

Chemical hazards such as solvents, adhesives, paints, toxic dust, or, more commonly, waste anesthetic gas are potential dangers to clinicians. However, identifying such exposures might not always be easy since some of the hazards might not be visible (gases) or have an odor. Techniques such as infrared spectrophotometry can be used to identify and quantify a gas leak. Long-term exposure to waste anesthetic gas may affect the antioxidant defense system and likely vital organ function.⁸ Preventative measures such as daily machine checks, effective scavenging and ventilation systems, proper vaporizer filling, and prompt cleanup of spills should be employed routinely.

In addition, the use of intraprocedural fluoroscopy has increased in both operating rooms and NORA sites. Radiation safety training for anesthesia professionals may be limited. The primary tenet of radiation safety is that exposure dose varies proportionally to the unprotected area of the person and inversely with the square of the distance.⁹ The small size of many NORA procedure rooms prohibits the anesthesia professional from positioning themselves at sufficient distance from the X-ray tube. Small room size also makes it challenging to add a rolling shield between the anesthesia professional and the radiation source.

Shielding with skirts fixed to the procedural table, rolling lead shields, or protective aprons worn by individual clinicians are essential to reduce exposure area for each person in the room. Eye protection decreases the incidence of cataracts.¹⁰ If lead glasses are not available, glass or plastic lenses do provide some reduction of exposure. A circumferential lead apron with thyroid shield protection is essential for anesthesia professionals as they frequently need to turn their backs to the X-ray tube.¹⁰ These aprons and thyroid shields should be provided by the institution for the use of clinicians working in a particular procedure suite.

Annual limits of radiation exposure are delineated by the National and/or International Council on Radiation Protection (NRCP, IRCP). Radiation dosimeters should be worn by all cli-

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nicians who have occupational exposure. Any individual who is pregnant or has greater than 10% of the recommended annual exposure should have monthly dosimeter assessments.¹¹ Institutions need to distribute dosimeters and monitor results, as well as assess the integrity of all lead shields annually.¹¹ Regular dosimeter assessment can be challenging given the large size of anesthesia departments and the multiple sites that are covered.⁹

Fortunately, multiple studies have confirmed that radiation exposure for anesthesia providers is generally well below established limits.⁹ However, when the X-ray tube is adjacent to the anesthesia professional, the clinician's exposure can be three times greater than the operator due to the anesthesia professional needing to move beyond any rolling shield to administer medications or attend to the patient.¹² In addition, the use of novel equipment or techniques in newer NORA procedures may result in inadvertently high radiation exposure, for example those that utilize continuous high-resolution imaging in the neurointerventional and cardiac interventional suites.¹²

CONCLUSION

As the number of nonoperating room procedures requiring anesthesia increases, anesthesia professionals are exposed to more hazards than in typical operating rooms. While many improvise ad hoc safety measures to avoid injury, there is a role for an organized, multidisciplinary effort to improve clinician safety. This includes being involved in room design, arranging equipment and associated cords/lines in the least obtrusive way, and following a safety checklist that accounts for appropriate equipment and removal or mitigation of physical hazards. Each anesthesia leader can work within their institution's system to reduce such risks.

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Annual Meeting of the American Society of Anesthesiologists

Anesthesia Patient Safety Foundation

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Emerging Medical Technologies— A Patient Safety Perspective on Wearables, Big Data and Remote Care

Saturday, October 14, 2023

1:15 pm-2:15 pm PDT



Moderator: Jeffrey Feldman, MD, MSE

APSF Launching Quantitative Neuromuscular Monitoring Course During ASA 2023 Meeting

(APSF.ORG/tei/qnm)

by Lawrence Caruso, MD; Nikolaus Gravenstein, MD; Debra Faulk, MD; Jeffrey Feldman, MD; David Lizdas, BS; and Samsun Lampotang, PhD

At the 2023 annual meeting of the ASA, the APSF, in collaboration with the ASA, is launching an online course on Quantitative Neuromuscular Monitoring (QNM) as the second offering of its Technology Education Initiative. The course is intended to provide and/or reinforce the knowledge and techniques required to safely and most effectively implement quantitative monitoring into practice. The course is largely aligned with the 2023 ASA Practice Guidelines for Monitoring and Antagonism of Neuromuscular Blockade;¹ the authors thank the ASA for permission to use the ASA 2023 practice guidelines and the ASA Task Force on Neuromuscular Blockade (NMB) for their effort and hard work in developing the practice guidelines.

The course utilizes guided simulation to help the learner understand: 1) the advantages of QNM compared with the traditional qualitative approach, 2) the difference between acceleromyography (AMG) and electromyography (EMG), the two quantitative monitoring technologies in current clinical use, and 3) how to use QNM to manage antagonism of NMB using either neostigmine/glycopyrrolate or sugammadex. The course is delivered online only and optimized for use with the Google Chrome web browser (Figure 1).

This course emphasizes patient safety and the central role of quantitative neuromuscular monitoring to ensure adequate recovery of the train-of-four ratio (TOFR) to \geq 0.9 of the baseline TOFR. Seven different topics, each requiring about 15 minutes, cover the essentials of quantitative neuromuscular monitoring and strategies during each phase of the anesthetic. While the topics are recommended to be done in sequence, they do not need to be done all at the same time.

The course is available online through the ASA Education Center. Any anesthesia professional or interested party can take the course free of charge by creating a guest account if they are not already an ASA member. While the actual course is hosted by the ASA, there is a landing page on the APSF website that acts as a web portal for using the QNM course. Inter-

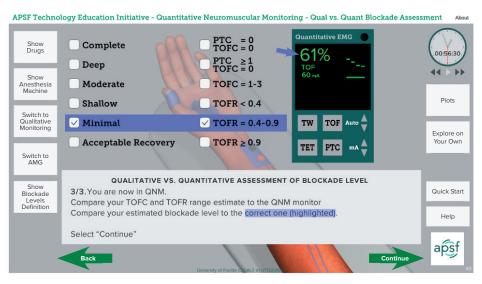


Figure 1: Snapshot of guided simulation from the APSF/ASA course on Quantitative Neuromuscular Monitoring (QNM). The user is guided on adjusting different settings on the QNM monitor and administering antagonists while visualizing their impact on neuromuscular function. (APSF.ORG/tei/qnm).

ested professionals are encouraged to begin by accessing the APSF website at <u>APSF.ORG/</u> <u>tei/qnm</u>.

The simulation approach is interactive and replaces traditional didactic teaching with a learning environment where the principles and functions of quantitative neuromuscular monitoring can be readily visualized and interactively explored. Get trained on the latest technology for neuromuscular monitoring and the most current practice guidelines. Don't wait! Sign up and take the course today!

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Preoperative Evaluation and Selection of Anesthesia Technique for Endoscopic Treatment of a Patient with Food Bolus Impaction or Foreign Object Ingestion

by George Tewfik MD, MBA, FASA, CPE, MSBA; Govind Rangrass, MD; James Dierkes MD, MBA; and Uma Munnur MD, MS

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BACKGROUND

Food bolus impaction and foreign object ingestion are aberrant clinical conditions that often require urgent intervention including endoscopy with either a push or retrieval technique.¹ Patients presenting with foreign body ingestion or impaction may subsequently develop catastrophic sequelae such as gastrointestinal perforation, bleeding, or ulceration.² In children, the most common objects ingested are coins, toys, magnets, and batteries, while in adults, bone or meat bolus impaction is the most common presenting pathology.³ Patient populations presenting with foreign object ingestion frequently include children, psychiatric patients, and prisoners, whereas food bolus impaction more commonly occurs in elderly patients with baseline esophageal pathology.⁴ Food impactions tend to be more common in males, and the most common associated pathologies are esophagitis, esophageal strictures and hiatal hernias, with more than half of boluses located in the lowest third of the esophagus.⁵ In contrast, foreign bodies are often lodged in the upper two thirds of the esophagus.^{6,7} Whereas foreign bodies in the upper portion of the esophagus pose additional risks including the inability to clear secretions and possible damage to the airway, potential sequelae of lower esophageal obstruction include esophageal erosion, mucosal damage, foreign body sensation, odynophagia, and sialorrhea.⁸ The level of risk to the patient ranges from minimal to life threatening depending on the ingested object or food, location, patient's underlying pathology, and time to treatment.⁸

Endoscopic retrieval or manipulation of food boluses or foreign objects in patients that suffer from acute obstruction has been shown to have high success rates, lower incidence of minor complications, and a reduction in the need for surgery or hospitalization.⁹⁻¹² The rate of complications increases with longer duration of obstruction and size/type of foreign body.^{13,14} For example, a sharp pointed food impaction has a higher risk of causing esophageal perforation and would benefit from early endoscopic intervention.^{15,16} Patients often present with dysphagia, odynophagia, vomiting and/or feelings of choking and gagging. Progression of an impaction or ingestion to an obstruction can lead to airway compromise, the inability to tolerate secretions, and even death.¹⁶

Various tools are used in conjunction with endoscopy to retrieve food or foreign bodies including baskets, retrieval forceps, polypectomy, snares and nets. It is important to note that foreign body impaction in the esophagus may be treated with flexible or rigid endoscopy, and the former technique often requires no anesthesia.¹⁷

ANESTHESIA FOR ENDOSCOPY

Sedation standards and practices for gastrointestinal endoscopy vary greatly between institutions, and in different legal jurisdictions.

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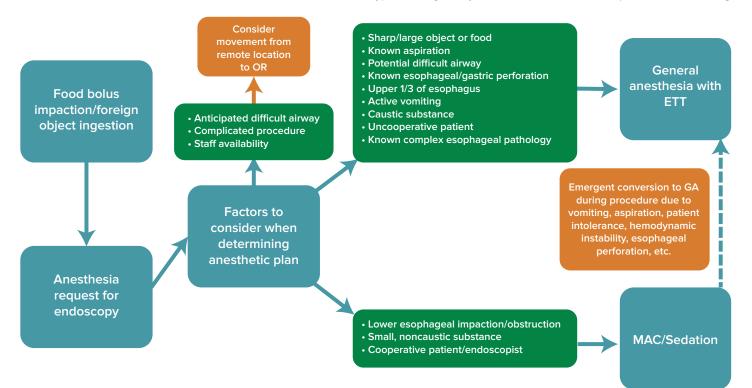


Figure 1: Algorithm for decision-making regarding the anesthetic care of a patient presenting for endoscopy with either food bolus impaction or foreign object ingestion. Consideration should be given to factors such as airway exam, procedure type, staffing, and logistics to determine anesthetic technique and proper setting for procedure. MAC: monitored anesthesia care, GA: general anesthesia, ETT: endotracheal tube

Anesthesia Type For Food Impaction Related Endoscopy

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Sedation may be provided by the anesthesiology team or nonanesthesia personnel, including nurses and gastroenterologists.¹⁸ Routinely used medications include titratable intravenous sedative-hypnotic agents, benzodiazepines, and opioids.

The 2018 guidelines released by the American Society for Gastrointestinal Endoscopy (ASGE) outline standards of care for patients undergoing procedures under the supervision of interventional gastroenterologists.¹⁹ Sedation may be conducted by nonanesthesia professionals ranging from topical anesthetic with minimal or no intravenous medication to moderate sedation with propofol and other intravenous medications (in locations where nonanesthesia professional administered propofol [NAAP] is sanctioned).²⁰ Nonetheless, the ASGE guidelines reports that anesthesia professional-administered sedation for endoscopy vields improved patient satisfaction, decreased distractions for the endoscopist, and increased procedure volume in the endoscopy unit because of shorter sedation and recovery times. Therefore, it is unsurprising that anesthesia services are frequently requested for endoscopic procedures, especially for endoscopic retrieval of a food bolus or foreign object.

CHOICE OF ANESTHETIC FOR FOOD BOLUS IMPACTION/FOREIGN OBJECT INGESTION

The optimal anesthetic technique for gastrointestinal procedures has long been debated with inconclusive results regarding superiority of one modality over another.²¹ When it comes to endoscopic removal of a foreign body or food bolus, the risk of aspiration during endoscopic manipulation is a critical concern for anesthesia professionals and should significantly influence the choice of anesthetic technique utilized. Nonetheless, these procedures are frequently performed using sedation instead of General Anesthesia (GA) with an endotracheal tube to secure the airway. There are risks and benefits to both GA and Monitored Anesthesia Care (MAC), though past literature is inconclusive regarding the superior approach. In one retrospective analysis, no difference in adverse events was found between conscious sedation using nonanesthesia personnel versus MAC and GA provided by anesthesia personnel.²¹ In this analysis, the most commonly occurring complications were surgical, including mucosal laceration and bleeding, while aspiration occurred much less frequently. Interestingly, though not surprising, 5.6% of their patient cohort could not tolerate conscious



sedation, and required conversion to anesthesia professional-guided MAC or GA. In another study, there was no difference in therapeutic results for patients undergoing endoscopic management of foreign bodies between GA and topical pharyngeal anesthesia.²²

It is critically important for anesthesia professionals to make a preoperative assessment regarding the presence or absence of a full stomach when considering intubation in all cases—a determination that may be complicated or obscured when managing a patient with food bolus impaction or foreign object ingestion. Generally, aspiration is more likely to occur when there is sufficient volume in the stomach for regurgitation, the lower esophageal sphincter is unable to protect the patient from retrograde movement of gastric contents, and upper airway reflexes are absent or blunted.²³ During endoscopic retrieval of a food bolus or foreign object under anesthesia, many or all of these conditions are likely present, categorically increasing the potential risk for aspiration. General anesthesia with an endotracheal tube is likely the safest option for perioperative care of patients suffering from both food bolus impaction and foreign body ingestion, and great care should be taken to consider deviation from this choice of anesthetic. After a thorough examination of the patient, assessment of the gastrointestinal status and discussion with the gastroenterologist/proceduralist, however, consideration may be given to other anesthetic options, as discussed below (though the option to convert to a secure airway with an endotracheal tube must always be available).

CHOOSING A SAFE ANESTHESIA PLAN

It is not clear if anesthesia professionals should routinely intubate for endoscopic removal of foreign bodies or food impaction. Certain situations may offer clear direction, but many circumstances are unique and require individualized assessment (Figure 1). If a patient has an obstruction or foreign body in the proximal esophagus, a secured airway may improve patient safety. Other situations that may prompt intubation include factors impacting the technical difficulty of retrieval and longer procedure duration such as ingestion of a caustic material, or exceedingly large or sharp foreign bodies; pediatric or combative patients; history of abnormal esophageal or gastric anatomy; or active or recent nausea and vomiting.²⁴ Anticipated complicated procedures and morbidly obese patients with a difficult airway may require care in the operating room in order to have access to advanced anesthesia and surgical equipment along with additional personnel to help if need arises.²⁵

In contrast, patients with suspected, but not confirmed, ingestion may be candidates for sedation. Patients who have radiographic confirmation of an object or food bolus that is in the distal esophagus and those with limited or no comorbidities, may demonstrate a trait profile that increases the likelihood of receiving sedation for the procedure.²⁶ Further considerations that may prompt use of sedation include absence of recent vomiting, small sized object/ food bolus, dull object, good patient compliance or willingness to agree with a sedation plan of minimal to moderate sedation, and provider/patient preference.⁹

Perioperative Care for Food Impaction-Related Endoscopy

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Considerations related to surgical technique may also impact anesthetic choice. For example, cap-assisted endoscopy (which uses a cap fitted to the end of the scope to depress mucosal folds and improve visualization) for treatment of food bolus impaction or foreign body ingestion has been shown to have increased rate of treatment success and shorter procedure time, which may increase willingness of the anesthesia professional to utilize a sedation anesthetic technique.^{27,28} Sedation may also be preferred in nonurgent endoscopies, such as those recommended for medium sized blunt objects, which may be delayed up to 72 hours from the time of initial ingestion.²⁴ Further, the use of such devices as an overtube, a device through which an endoscope is inserted, may help to reduce the risk of aspiration and mucosal injury, and may also influence decision-making by the anesthesia professional.^{29,30} The overtube serves to protect gastrointestinal mucosa from trauma and decreases the risk of aspiration by providing an occlusive conduit from the esophagus to outside the oral cavity.^{29,31}

An important consideration prior to anesthetic care for endoscopy for food bolus impaction and foreign object ingestion is logistics of the treatment facility. Often, these procedures are performed in the emergency room, gastrointestinal procedure suite, hospital bed, or other remote location outside of the operating room. This limitation introduces such complicating factors as space constraints, difficulty accessing the patient's head, poor lighting, limited monitoring, lack of advanced airway equipment, lack of experienced ancillary staff, and inadequate communication with personnel involved in patient care.³² Past literature has shown that emergency airway management outside of the operating room can be challenging and increases the risk of adverse events.³² Patients with anatomic variants, poor functional reserve and high risk for aspiration who present for emergency endoscopy likely should be moved to the operating room and should undergo GA with an endotracheal tube to limit risk of such adverse events.³² Successful anesthesia for endoscopic procedures in remote locations requires adequate monitoring equipment, devices for delivering anesthetic agents, and the ability to oxygenate, as well as a thorough understanding of the surgical procedure and its associated invasiveness.³³

SPECIAL SAFETY CONSIDERATIONS

Communication

Effective communication is essential for the safe perioperative care of patients undergoing endoscopy for retrieval of a food bolus or foreign object. This includes communication with the proceduralist, patient, family members, nursing staff, technologists, and administrative personnel. It is necessary to ensure proper communication to facilitate timely care, confirm available resources, and coordinate care between preoperative, intraoperative, and postoperative staff, as well as the patient's primary care service in the medical facility. When the decision has been made to proceed with MAC in a remote location, the anesthesia professional must ensure that the equipment and personnel are in place to convert to general anesthesia whenever required by the patient's medical condition. In addition, given the potential for encountering a difficult airway (especially in a remote location), equipment such as video laryngoscopes, fiberoptic bronchoscopes, and intubating LMAs should be available to assist with the intubation.

Postoperative Care

The anesthesia professional must also pay special attention to the postoperative disposition of the patient afflicted with a foreign object or food bolus impaction. Due to the possible complications of both conditions affecting the gastrointestinal tract, these patients are at increased risk of such events as esophageal or gastric perforation, gastrointestinal bleeding, and aspiration. These potentially catastrophic sequelae necessitate close monitoring by qualified personnel for signs such as hypoxemia, wheezing, and hemodynamic instability. Ancillary services should also be available for patients such as thoracic surgery for treatment of esophageal perforation causing pneumomediastinum or esophageal rupture. In addition, critical care services should be available for patients who suffer systemic compromise requiring elevated and invasive support.

CONCLUSION

There is no uniform approach to anesthetic care for endoscopic procedures to treat food bolus impaction or foreign object ingestion. One must consider numerous factors prior to initiating care of these patients, and effective communication with the patient, endoscopist, and ancillary staff is extremely important. Proper planning is necessary when the procedure is conducted in a remote location along with backup plans in place for some of the potential complications such as failed endoscopist-administered sedation, aspiration or airway obstruction, or procedural complications such as perforated esophagus requiring surgical intervention. Nonetheless, these procedures may be safely performed if the anesthesia team utilizes a systematic approach to evaluate and treat these patients, such as the framework proposed by the authors.

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Barbara M. Dilos

Achieving a Successful Patient Safety Program with Implementation of a Harm Reduction Strategy

by Jonathan B. Cohen, MD, MS

HEALT

In March of this year, the U.S. Food and Drug Administration (FDA) approved naloxone hydrochloride nasal spray for over-the-counter, nonprescription use. This move was consistent with longstanding recommendations by the American Society of Anesthesiologists (ASA) and testimony given before several of its committees by ASA member Bonnie Milas, MD.¹ The approval of naloxone for over-the-counter use by the Food and Drug Administration represents a nontraditional approach to managing opioid use, overuse or abuse, an approach referred to as "harm reduction."

Whereas a "prevalence reduction" approach focuses on abstinence from behaviors that create risk, a harm reduction approach focuses on ameliorating the harmful consequences of the behavior.^{2,3} Although not without opposition from those who find the behavior morally objectionable, harm reduction presents a pragmatic approach to the mitigation of injury when behavior is difficult to modify.² While harm reduction practices involving substance use are considered by some to be controversial, health care professionals routinely engage in other forms of harm reduction that are less contentious.³ A common example of this harm reduction approach is the prescription of cholesterol-lowering and antihyperglycemic medications to patients whose diet and exercise regimen are not optimal.

When we consider strategies to successfully address human error in anesthesiology, we can draw parallels to some of the core elements of a harm reduction approach (Table 1).⁴

THE PRACTICE OF ANESTHESIOLOGY INVOLVES BEHAVIOR WHICH CAN LEAD TO HARM

The anesthesia work environment is complex, time-constrained, and stressful. Anesthesia professionals must negotiate the interactivity

between the patient, equipment, medications, tasks, organization, and the surgical team. Simultaneously, they must remain vigilant, be able to multitask (or, more appropriately described, be able to rapidly switch between several tasks), and take actions with life-ordeath consequences.⁵⁻⁷ The successful management of these multiple factors and how they affect each other is likely achieved the same way that pilots become adept at managing concurrent tasks, while simultaneously integrating unplanned tasks and rescheduling tasks. Such management requires substantial practice.⁸ In experienced pilots this strategy becomes largely automatic and does not require significant mental effort.⁸ Similarly, in studies involving anesthesia professionals, novices reported a higher degree of subjective workload than did experts for equivalent task loads.⁹ While great strides have been made over the years to improve the safety of patients undergoing anesthesia, the very nature of anesthesiology and the procedures for which patients require anesthesia will always have inherent risk, the

 Table 1: Analogy of Harm Reduction Approach with Substance Use and Anesthesia

 Patient Safety.

Substance Use Harm Reduction	Application to Anesthesia Patient Safety
Acknowledgement that risky behaviors (e.g., substance use) can lead to harm.	Acknowledgement that the practice of anesthesiology involves behaviors which can lead to harm.
Establishes a morally neutral approach to substance use.	Establishes a morally neutral approach to human error.
Success must involve targeting more than solely complete abstinence from substance use.	Success must involve targeting more than behavior preceding harm.

elimination of which will never be completely possible. The harm which may occur as a result of anesthesia exists along a spectrum. Although the most severe degrees of harm are rare, it is nearly unavoidable for many anesthesia professionals during their career. It is also important to recognize that the harm which occurs to patients from error also extends to, and can have long-last effects upon, the anesthesia professional.¹⁰

MAKING ERRORS IS MORALLY NEUTRAL

The concept of human imperfection has been appreciated since biblical times.¹¹ According to Shappell & Wiegmann, it is unreasonable to expect error-free performance from humans because, by their very nature, they make mistakes.¹² Perrow estimated that human error accounted for 60-80% of accidents, an estimate similar to the work done by Cooper in the analysis of anesthesia-related incidents.^{13,14} In general, we make between 5 and 20 errors per hour depending on the type of work (manual vs. cognitive) and the circumstances in which the work is accomplished in (routine vs. urgent).¹⁵ The majority of these errors are prevented from causing harm by the systems in which we work, systems which include the very person making the error. The barriers, recoveries, and redundancies which prevent these errors from resulting in harm reflect the flexibility and resilience of the system. However, when certain circumstances involving the anesthesia professional such as fatigue, distraction, or the misinterpretation of clinical data or a warning alarm combine

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with certain patient factors, such as extensive comorbid disease and diminished physiologic reserve, the adaptive capacity of the system is no longer maintained, and harm can result.

Medical errors are often viewed as a moral failing, with a focus on blaming the individual for not being attentive enough or behaving in a way that is inconsistent with information which is only obvious to those viewing the situation with the benefit of hindsight.^{16,17} Health care professionals along the entire spectrum, from the most inexperienced, junior member of the team to the most senior are all prone to making errors.¹⁸ We've known for decades that the "blame approach" does not change the incidence of errors, rather it cloaks it in secrecy and makes the underlying causes difficult to address.¹⁹ Despite this knowledge, blame for making errors remains prevalent.^{20,21} It is important to consider that behavior can be seen as the cause of accidents even if the behavior itself is not attributed to impropriety or intentions of harm.²² The use of punitive language to describe this behavior is a symptom of a punitive safety culture.²⁰ Creating a "Just Culture" is essential to the overall development of a robust safety culture in an anesthesia department.²³ A Just Culture is not a system that is free of accountability, but rather one in which accountability is appropriately balanced between the individual and the system within which the individual practices.²⁴ It is possible to hold individuals accountable without blame, and a similar model has been suggested for substance use.^{25,26}

WE MUST RECOGNIZE THAT ONLY TARGETING BEHAVIOR PRECEDING HARM IS NOT PRACTICAL

Attempts to eliminate error-prone behavior continue to fail, and this approach is no longer accepted as a viable tactic by human factors experts.²⁷ Resilience engineering and the Safety-II view reinforce this, as the processes underpinning human error are the same as those leading to acceptable outcomes, the difference being everyday performance adjustments.^{28,29} The Safety-II approach represents a fundamental change in the way that safety is viewed, shifting from examining what goes wrong (the traditional/Safety-I approach) to looking at what is necessary for acceptable outcomes to occur.²⁹ The key to understanding how adverse outcomes occur is to have a thorough understanding of the human performance variability that is necessary for a satisfactory outcome.²⁹ In this way, Safety-II is a proactive approach to safety management, as opposed

Table 2: An Example of Harm Reduction in Perioperative Care: Wrong-Sided Nerve Block.

Harm Reduction Principle	Goals	Tactics	Example
Acknowledge that the practice of anesthesiology involves behavior which can lead to harm.	Reduce the risk of harm from errors to both patients and anesthesia professionals.	Development of a robust safety program to manage risk of harm to patients, including providing care for the patient/family as well as the anesthesia professional. ³³⁻³⁵	After a wrong-sided nerve block, the patient was immediately cared for, and the event was promptly reviewed and disclosed to the patient and family. Support was provided to the anesthesia professional involved.
Establish a morally neutral approach to human error.	Health care adoption of the notion that error is ubiquitous, unavoidable, and, therefore, not blameworthy. ²⁷	Establish a Just Culture, which supports reporting adverse events, which is a critical step toward reducing harm. ³⁶	The anesthesia professional understood that by reporting the event, systemic issues that contributed to the error occurring might be reduced.
Success must involve targeting more than the behavior preceding harm.	Focus on preventing harm from error.	Target systems-level solutions that create barriers to prevent error, recoveries to capture error and redundancies to limit the effects of error when it occurs. ^{5,27,37}	As a result of the adverse event review, nerve block time-outs were created that verified the procedure using multiple sources of information immediately prior to the block (including the patient, when possible) and identified the site with a visible mark prior to performance of the procedure. ³⁸

to the reactive nature of the Safety-I approach. One of the essential components of Safety-II is attention to the system that shapes the variability in human performance. Harm reduction efforts that target modifications to the system are known to be more durable and effective than those that target modifying the behavior of individuals.³⁰

INTEGRATING HARM REDUCTION PRACTICES IN ANESTHESIOLOGY SAFETY PROGRAMS

In summary, decreasing the harm from substance use and human error are problems that are intractable and resistant to solutions.³¹ This doesn't mean that hope is lost, but rather that we need to approach these problems with different strategies than what we have employed in the past (Table 2). The behavior involved in the delivery of anesthesia can lead to harm, not just to patients, but also to ourselves. Errors are ubiquitous and anesthesia professionals of all experience levels will make them. When human behavior falls short of perfection, as it inevitably will, blame needs to be withheld as it will not prevent recurrence; making errors needs to be treated as morally neutral. A Just Culture approach of balancing accountability between the individual and the system provides a framework for reviewing harm events as well as designing systems that are more resilient. Since the same behaviors that lead to successful outcomes also can lead to harm, we must focus the majority of our efforts on designing systems that prevent harm rather than human error. Finally, we must train anesthesia professionals in safety as we would in any other field of science, and partner with safety professionals to better understand our complex systems.³²

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Annual Meeting of the American Society of Anesthesiologists

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



American Society of Anesthesiologists



Integrating Behavior and Technology for Anesthesia Patient Safety

Saturday, October 14, 2023 3:45 pm–4:45 pm, PDT



Presented by: John Eichhorn, MD, MPH

Sustainable Anesthesia: Limiting Waste, Maximizing Resiliency

by Molly M.H. Herr, MD, and Leal G. Segura, MD

In anesthesiology, the use of single-use devices has sky-rocketed over the last two decades. Single-use devices used in anesthesia practice, including laryngoscopes, video laryngoscopes, blood pressure cuffs, medical gowns, operating room hats and attire, and pulse oximetry probes are often discarded immediately after one-time use. In 2019, the U.S. disposable medical device market was already a \$66.9 billion industry, and the industry continues to grow, currently increasing at a compound annual growth rate of 16.7%.¹

Manufacturers tout the ease and safety of single-use products. Advocates suggest easier infection control with their use. Ambiguity and changes in processing requirements for medical equipment have led many health care organizations to default to disposable devices over fear of citations by accrediting bodies.

Recent pandemic-related supply chain disruptions starkly exposed the dangers of heavy reliance on disposable devices. Health care systems often keep relatively low supplies of these single-use devices, reordering only short-term supplies reflecting a "just in time" mentality focused on keeping costs low. Anesthesia professionals have faced occasional medication and product shortages in the past, but the frequent and profound shortages of equipment, supplies, and medications over the last three years is an abrupt departure from modern clinical practice in the United States. As anesthesia practices scramble for alternative equipment and supplies, they may be forced to use second- or third-line devices or medications, potentially creating significant patient safety concerns related to the frequent introduction of new and unfamiliar supplies.

These product shortages, and the supply chain fragility they expose, should prompt an evaluation of disposable device usage. Further, an increasing awareness of anesthesiology's outsized environmental footprint, and the consequent impact on public health, has prompted many health care systems to re-evaluate purchasing processes to decrease the

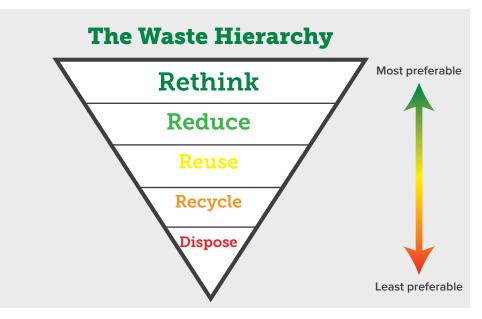


Figure 1: Recommended order of actions to manage waste, from most to least environmentally preferred. Goals of this process are to save resources and energy, reduce waste and its toxicity, and save money for health care systems and patients.

massive waste and greenhouse gas (GHG) emissions produced from surgical practices.

In this review, we outline methods to increase both sustainability and supply chain resiliency in anesthesiology practices based on evidencebased analysis of product safety, infection risk, and greenhouse gas emissions (GHG) related to product manufacturing, use, and disposal. Ultimately, maximizing the utilization of reusable devices promotes patient safety by reducing the risk of shortages of essential products. Reusable products confer a reduced environmental footprint by creating less physical waste and offer the potential of enormous cost benefits for health care systems.

Building sustainable, resilient, and cost-effective anesthesia practices demands an understanding of product costs and resource utilization. Life cycle costing and life cycle assessments are important concepts that are helpful for practice leaders who are evaluating purchase decisions. These life cycle concepts

Table 1: Terms Related to Sustainable Device Purchasing.^{2,6}

TERMS	DEFINITION
Life Cycle Assessment (LCA)	An internationally standardized modeling tool evaluating the cradle-to-grave environmental impact associated with all states of a product's life. Includes raw material extraction and processing, manufacturing, distribution, use, and eventual waste or recycling.
Life Cycle Costing (LLC)	The process of compiling costs of ownership over the lifetime of a product.

are dependent on the number of times a product is used and are determined by productrelated energy costs, GHG emissions, and economic costs over its lifespan (Table 1).² Additionally, it is imperative for health care organizations to understand waste management in the context of environmental impact, patient and community safety, and cost benefit. The Waste Hierarchy (Figure 1) is one tool practice leaders can utilize when evaluating potential device purchases.³ For example, the waste hierarchy suggests that a properly cleaned, re-used pulse oximetry probe offers less environmental impact (and is cheaper to hospital systems) than a recycled or discarded probe. Successful waste management improves the health of communities by reducing landfilled and incinerated waste, both of which may produce soil, water, and air toxins and other hazardous by-products. A waste management program that prioritizes properly cleaned, reusable devices improves planetary health by decreasing fossil fuel usage, carbon dioxide emissions, and energy required for the manufacture, transport, and disposal of these single-use items.

SURGICAL SITE INFECTION AND REUSABLE PRODUCTS

Prevention of surgical site infections (SSIs) is a priority for any health care system. SSIs are associated with an increased hospital length of

Reusable vs. Disposable Anesthesia Equipment

From "Limiting Waste," Preceding Page

stay, increased risk of readmission, and increased morbidity and mortality.⁴ While easy infection control is touted as a benefit to disposable device use, there is no evidence that reusable equipment leads to increased SSI when appropriate cleaning protocols are performed. In fact, the Center for Disease Control and Prevention has requirements for device disinfection and sterilization based on the Spaulding Device Cleaning Classification. This system classifies cleaning techniques and reprocessing methods for specific devices according to level of patient contact and infection risk during use (Table 2).⁵ In addition, all medical equipment should be cleaned in accordance with the manufacturer's instructions for use, which provide additional guidance to maintain device safety and longevity, based on tested cleaning protocols.

COMMONLY USED DISPOSABLE AND REUSABLE ANESTHESIA PRODUCTS

Laryngoscope Handles and Blades

Evaluations of the life cycle assessment and total life cycle costs of reusable and disposable laryngoscope handles and blades show significant environmental and cost savings with reusable equipment,⁶ without compromising patient safety when cleaned according to established guidelines.

According to the Spaulding Classification, laryngoscope handles may be considered either low or moderate infection risk as consensus varies between professional organizations, requiring either "low-level" disinfection, using chemical wipes or 70% alcohol, or "highlevel" disinfection, using chemical reprocessing. Either protocol still confers environmental benefit over single-use laryngoscope handles. For example, a disposable metal handle produces 20 times more GHG emissions per use than a low-level disinfected handle and nearly 27 times more GHG emissions than a high-level disinfected reusable steel handle, assuming a life span of 4000 uses. Reusable laryngoscope blades, which require high-level disinfection at minimum, are still environmentally preferable over single-use metal blades. These reusable blades produce between 2-7 times less GHG emissions per use, depending on sterilization or high-level disinfection, respectively.6

Safety data showing a clear benefit of disposable laryngoscopes over adequately cleaned reusable laryngoscope handles and blades are lacking. Further, there is no evidence to suggest infection transmission in the US from reusable handles or blades,

Table 2: Spaulding Device Cleaning Classification.

Level	Infection Risk	Description	Examples	Required Processing Methods
Critical	High	Enter sterile areas, including the vascular system	Surgical instruments, implants	STERILIZATION High-pressure steam
Semi- critical	Moderate	Contact mucous membranes or broken skin	Laryngoscope blades, rigid/flexible endoscopes, video larynoscope blades	HIGH-LEVEL DISINFECTION (HLD) Chemical reprocessing, vaporized hydrogen peroxide, glutaraldehyde, etc.
Non- critical	Low	Contacts intact skin	Larynoscope handles*, blood pressure cuffs, stethoscopes, video laryngoscope handles	LOW-LEVEL DISINFECTION (LLD) Wipe disinfection, Sani- cloths, 70% isopropyl alcohol, quaternary ammonium

*There is some controversy over laryngoscope handle cleaning between organizations: some designate handles as noncritical devices, while others do not delineate between the blade and handle, and therefore, designate the entire device as semicritical. Some laryngoscope manufacturers have new handles compatible with HLD that do not require disassembly and are immersible, along with LLD options in the Instructions for Use (IFU).^{5,6}

appropriately cleaned according to Spaulding Classification criteria and the manufacturer's instructions for use.⁷

Case reports of infection transmission in neonatal intensive care units describe inadequately disinfected laryngoscopes where current cleaning protocols were not followed.⁸ Older data show contamination of reusable blades and handles, but the majority of studies were judged to be very low or low quality, with inconsistent cleaning protocols.⁹ A study examining laryngoscope handles cleaned with low-level techniques demonstrated no pathogenic bacterial or viral colonies and only rare to few nonpathogenic bacterial colony growth, which decreased in samples as the study continued, perhaps reflecting increased attention to handle cleaning during the study period.¹⁰ Further, this bacterial contamination is of unclear significance, given that 50% of sterile fields are contaminated within a few hours, even in empty operating rooms,¹¹ and bacteria have been cultured from sterile trays immediately after opening.¹² In addition, anesthesia personnel routinely use laryngoscope handles without sterile gloves and even single-use devices are opened, touched, and contaminated during OR set-up. These studies highlight the importance of high-quality, careful protocolized cleaning and reprocessing.

When the lifetime costs of reusable laryngoscopes, including those related to reprocessing and device attrition, are evaluated against disposables, a reusable handle needs to be used only 4–5 times for cost benefit compared to a disposable handle, and reusable blades only 5–7 times compared to single-use blades. In one year of clinical practice, reusable handles and blades confer significant savings to health systems, regardless of cleaning protocol, despite initial higher upfront costs.⁶

Reusable products do not just confer cost benefit, they also may improve patient safety by safeguarding against critical shortages. The SARS-CoV-2 pandemic led to widespread shortages in single-use plastic video laryngoscope blades. Many institutions adapted by reprocessing blades internally or through thirdparty reprocessing companies, demonstrating the supply chain vulnerability of single-use products versus reusable products, particularly during periods of high demand. The pandemic experience highlighted that reprocessing of single-use devices can be performed safely. External third-party reprocessing is highly regulated by the FDA, designed to restore products to their original quality, function, and sterility, while maintaining safety warranties. Even with stringent protocols, reprocessed device costs are still half the price of new equipment.13

BLOOD PRESSURE (BP) CUFFS

Life cycle data suggest reusable BP cuffs have far less environmental impact over disposable cuffs. Reusable BP cuffs are environmentally better in all clinical use settings, with a wide variety of cleaning protocols, generating close to 40 times fewer GHG emissions than disposable cuffs over their lifetime. Life cycle cost analysis demonstrates that reusable BP cuffs are far cheaper than disposable cuffs over their lifetime in both outpatient and procedural areas.¹⁴

Safety Benefit of Disposable vs. Reusable Devices Not Confirmed

From "Limiting Waste," Preceding Page

From a patient safety perspective, there are no data that reusable blood pressure cuffs are responsible for increased infection versus disposable cuffs. However, inadequately disinfected reusable cuffs may be contaminated by bacteria.¹⁵ Single use cuffs may also be contaminated by the hands of health care workers if they are not frequently sanitized. Both scenarios emphasize the importance of protocolized cleaning techniques and handwashing. As noncritical devices, defined by the Spaulding classification, BP cuffs require low-level disinfection between patients.

Gowns (surgical and isolation)

Reusable surgical gowns and isolation gowns confer significant patient safety benefits because they are less vulnerable to critical shortages. Dramatic supply chain advantages emerged during the SARS-CoV-2 pandemic. In fact, institutions with reusable isolation gowns during the pandemic had a protective advantage compared to those institutions using disposables, when many resorted to garbage bags to provide personal protective equipment in the face of global shortages.

Further, reusable gowns are more durable, offering improved infection protection and substantial cost savings due to their durability and sustainability. A comparison of disposable vs. reusable medical gowns (laundered up to 75 times, according to CDC guidelines) showed that lower-level disposable gowns did not meet the industry standard, the Association of Advancement Instrumentation PB70 Performance Specifications, for impact penetration water resistance. In addition, all the tested disposable gowns (Level 1, 2, and 3) failed to meet the standard American Society of Testing and Materials performance requirements for breaking strength. The reusable gowns performed much better, meeting both performance requirements throughout 75 washings.¹⁶

The environmental footprint of reusable gowns is far smaller than disposables: one life cycle assessment showed that the use of reusable surgical gowns decreased natural resource energy consumption by 64%, GHG emissions by 66%, blue water use by 83%, and solid waste generation by 84%. Blue water consumption is water removed from the water supply and not returned.¹⁷

Similar analyses confirm the environmental benefit from reusable isolation gowns, which confer a 28% reduction in energy consumption, a 30% decrease in GHG emissions, a 41% reduction in blue water consumption, and a 93% reduction in solid waste generation.¹⁸

OR Hats and Arm Coverings

Over the last decade, guidelines regarding head coverings for operating room personnel have shifted, with current recommendations favoring clean, but not necessarily disposable head wear. Further, from a patient safety perspective, most published evidence suggests that reusable hats confer at least equivalent, if not better, infection protection with a far smaller environmental footprint.

In 2015, the Association of periOperative Registered Nurses released guidelines on OR attire directed at decreasing surgical site infection (SSI) risk. The guidelines, requiring disposable bouffant hats and long sleeves among all nonscrubbed personnel, were accepted by accrediting bodies, including the Centers for Medicare and Medicaid Services, despite no definitive evidence to support the recommendation.¹⁹

These guidelines were followed by a series of published studies demonstrating no infection benefit with disposable versus reusable hats. One study of 70 surgeons performing over 6000 ventral hernia repairs showed no significant difference in surgical site infection with respect to surgeon head wear.²⁰ Another study showed potential safety benefit for nondisposable hats, showing that airborne particle contamination was significant lower with cloth "skull" hats versus disposable bouffants. Passive microbial shedding was also significantly higher with disposable bouffants compared to disposable skull caps and other cloth hats. In fact, disposable bouffant hats were the most permeable and had largest pore size.²¹

Current guidelines from multiple organizations, including the American Society of Anesthesiology, American College of Surgeons, and Association of periOperative Registered Nurses, now confirm the lack of scientific evidence showing any association between head covering type, extent of hair coverage, and SSIs, with new recommendations simply favoring clean surgical coverings during procedures.²²

It is unclear why the use of disposable hats and gowns remains so entrenched, despite the lack of evidence for improved infection control. While disposable products may seem cheaper, cost analyses demonstrate that these items confer high costs to health care systems. In a recent study of over 12,000 matched pairs of surgical patients, more strict attire of disposable bouffants, disposable beard covers, and disposable long-sleeved jackets among nonscrubbed operating room personnel drove total attire costs up 10 to 20 times per person entering the OR without improving surgical site infection risk. $^{\rm 23}$

Pulse oximetry probes

The use of disposable pulse oximetry probes is widespread and reflexive in anesthesia practices. From an individual patient safety standpoint, there is a paucity of data showing any difference in the safety profile and accuracy between reusable versus disposable pulse oximetry probes, nor any data showing increased infection risk with appropriately cleaned reusable probes versus disposable probes. Further, increased availability of reusable pulse oximetry probes may improve safety in resource-poor countries. Pulse oximetry has been included on the World Health Organization's Surgical Safety Checklist since 2007, but is still missing from 15% of operating rooms in resource-poor settings.²⁴ Further, decreased waste generation and resource utilization with the use of reusable pulse oximetry probes can lead to improved community and planetary health.

The potential clinical benefits of reusable probes are matched by cost savings to clinical practices, as well. Data from emergency medicine literature suggest that reusable pulse oximeters may provide equivalent monitoring without safety concerns and with less costs. One quality improvement project performed by an emergency department with roughly 70,000 annual patient visits showed a 56% reduction in cost with reusable pulse oximeters. Likewise, monthly pulse oximeter acquisition costs dropped by \$30,000.25 Another analysis of an emergency medicine department with 55,000 annual visitors demonstrated annual savings of \$129.000 with reusables. To generate costsavings, a reusable monitor needed to be used 22 times.26

CONCLUSIONS

As highlighted, no evidence suggests that single-use devices in anesthesiology with low or intermediate infection risks provide better or safer care for our patients compared to appropriately cleaned reusable devices. Rather, patient safety is put at risk when heavy reliance on disposable clothing, equipment, and devices renders hospital systems vulnerable to severe supply chain shortages, prompting scrambles for products which may be inferior, unfamiliar, and more costly. Further, massive amounts of disposable medical equipment are either incinerated or go to landfills, with obvious environmental and public health consequences. As such, sustainability standards, greenhouse

Disposable vs. Reusable Perioperative Devices (cont'd)

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gas emissions, lifetime costs, and supply chain resiliency should be emphasized during purchasing decisions in hospital systems, along with evaluation of device quality, safety, and ease of use.

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The authors have no conflicts of interest.

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The APSF is eager to connect with patient safety enthusiasts across the internet on our social media platforms. Over the past year, we have made a concerted effort to grow our audience and identify the best content for our community. We've seen increases in followers and engagement by several thousand percent, and we hope to see that trajectory continue into 2024. Please follow us on Facebook at https://www.facebook.com/APSForg/ and on Twitter at https://twitter.com/APSForg. Also, connect with us on Linked In at https://www.linkedin.com/company/anesthesia-patient-safety-foundation-apsf-. We want to hear from you, so please tag us to share your patient-safety-related work, including your academic articles and presentations. We'll share those highlights with our community. If you are interested in joining our efforts to amplify the reach of APSF across the internet by becoming an Ambassador, please reach out via email to Emily Methangkool, MD, the APSF Ambassador Program Director at methang-kool@apsf.org, or Amy Pearson, Director of Digital Strategy and Social Media at pearson@apsf.org. We look forward to seeing you online!



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

SPOTLIGHT on Legacy Society Members



Steve and Janice Barker

After my first career in aerospace engineering, I went into medicine in my mid-thirties and became an anesthesiologist. Throughout my second career, I have tried to apply lessons from the first one to improve patient safety. Medicine and particularly anesthesiology can learn a great deal from aviation and getting those lessons into clinical practice has been a major goal for me. Early on in this mission, I discovered that the APSF has many of the same goals I have, and that APSF is very supportive of using novel approaches to improve patient safety. I found that Bob Stoelting, Mark Warner, and now Dan Cole are very open-minded in this respect, and all of the APSF staff have been very supportive. About ten years ago I helped organize the Patient Safety Movement Foundation (PSMF), founded by Joe Kiani of Masimo. APSF and PSMF (an alphabet soup mouthful) have much in common in our missions and strategies, and I have tried to help broker increasing collaboration between the two. APSF has been open to this idea, and together we have moved forward with the relationship.

In summary, the APSF mission is my mission, the APSF leaders and members are my good friends, and they are the people with whom I want to work. I am therefore honored to become a member of the Legacy Society as one more way I can support the APSF.



Jeffrey and Karma Cooper

As a founding member of the APSF Executive Committee, I take great satisfaction in the sustained leadership and success of this organization in advancing perioperative patient safety.

What is so remarkable and has brought me great personal pleasure and joy, is the continuous, unwavering, extraordinary mutual respect, support, and camaraderie of the Executive Committee. Despite almost complete replenishment of its composition more than once over the more than 30 years since the APSF's inception, that team has sustained those qualities and continued to evolve and work effectively. The current board and leadership are a new generation; I have no doubt that they will continue that legacy of working together effectively, of innovating to meet the new challenges ahead and enjoying their working together. My expectation is that there will be a need for APSF far into the future because it will continue to evolve to meet the future needs of patient safety. Our trust in that is secure; thus, Karma and I are confident that our pledge of support from our estate will be a worthy investment in the future.



Dru and Amie Riddle

"No one shall be harmed by anesthesia care." The mission of APSF resonated deeply with us as we have dedicated our entire professional careers to ensuring safe care for patients. APSF is a critical part of accomplishing this goal, and we are proud to support the Foundation in a way that we hope will be long-lasting. Legacy giving is critical to any organization, and we are honored to support an organization that aligns with our personal and professional values.

Dru is a Certified Registered Nurse Anesthetist (CRNA), and Amie is a Psychiatric Mental Health Nurse Practitioner (PMHNP).

An abiding belief in safeguarding the future of anesthesiology.

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

APSF recognizes and thanks these inaugural members who have generously supported APSF through an estate or legacy gift. For more information about planned giving, please contact Sara Moser, APSF Director of Development at: moser@apsf.org.

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