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# NEWSLETTER

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# Position Statement on Criminalization of Medical Error and Call for Action to Prevent Patient Harm from Error

*by the APSF Criminalization of Error Task Force:*
*Jeffrey Cooper, PhD; Brian J. Thomas, JD; Elizabeth Rebello, MD; Paul Lefebvre, JD; Karen Wolk Feinstein, PhD; Lynn Reede, DNP, MBA, CRNA, FNAP; Seema Kumbhat, MD; and Steven Greenberg, MD, FCCP, FCCM*

The Anesthesia Patient Safety Foundation (APSF) is the first organization created to focus solely on patient safety. For more than 35 years, the APSF has played a significant role in the dramatic reduction of harm from anesthesia and has advocated for perioperative patient safety. We are deeply saddened and concerned by each patient adverse event that results in harm during any aspect of health care delivery, especially when the causes are preventable. We offer our heartfelt condolences to all patients and their loved ones who have been harmed by preventable adverse events. We recognize that errors occur and that health care professionals have responsibility for those errors, in particular, recognizing them and working to prevent them from reoccurring.

In the interest of patient safety, the APSF feels strongly compelled to comment on the issue of criminalization of medical error.[1,2,3] The issue recently received much attention due to the conviction of a Tennessee nurse for gross neglect of an impaired adult and criminally negligent homicide after a patient died as the result of a medication error and failure to monitor. The Court granted judicial diversion and sentenced the nurse to three years of supervised probation.[4] We believe the prosecution and conviction of the nurse involved was counterproductive to the pursuit of prevention of harm to future patients and health care professionals. However, we strongly advocate for systemic changes that will enhance health care's culture of safety and will reject the acceptance of "normalization of deviance" that enables unsafe medical practices.[5]

In this position statement, we assert our reasons for these beliefs. Yet, we know that this recent event is representative of an incalculable number of similar events that occur in health care. It is thus equally important that we focus on preventing errors and system failures that lead to such tragic outcomes. We ***call to action*** all health care systems, professional societies, health care professionals, and appropriate government agencies to take energetic, collaborative action to create and continuously improve systems of care so that such errors are nearly impossible.

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# Editorial: APSF's Statement About Criminalization of Medical Error and Call to Action Against Preventable Adverse Events

*by Jeffrey Cooper, PhD; Brian Thomas, JD; Elizabeth Rebello, Rph, MD, FASA, CPPS, CMQ; Paul Lefebvre, JD; Karen Feinstein PhD, MSW; Lynn Reede, DNP, MBA, CRNA, FNAP; Seema Kumbhat, MD; Steven Greenberg, MD, FCCP, FCCM*

Almost five years ago, Charlene Murphey, a patient at Vanderbilt Medical Center, died from a series of system failures and errors, a classic "Swiss Cheese" event.[1] The local prosecutor decided to do something extremely rare, to take legal action against the nurse who administered vecuronium in place of midazolam, leading to Ms. Murphey's death.[2] The nurse, who had already lost her job and license, was convicted of gross neglect of an impaired adult and criminally negligent homicide, but ultimately sentenced to three years' probation.[3] Via a position statement that is published in full in this issue of the *Newsletter*, APSF is one of several organizations that is speaking out against the criminalization of errors made by health care providers in the process of delivering care with good intentions. However, APSF believes that the more important action in response to this and many similar adverse events, especially those involving medication errors and failure to monitor, is for all health care systems, professionals, and regulatory bodies to identify and increase activities and interventions that will prevent errors leading to patient harm.

What happened on that fateful day in 2017? According to reports from several media outlets, it is a complicated story that may seem egregious, but on close examination is familiar in tragic, preventable outcomes. Basically, RaDonda Vaught, RN, an experienced ICU nurse, was the resource ("help all") nurse called to the MRI Department that was short-staffed. She was tasked to administer midazolam to Charlene Murphey to reduce anxiety, under the classic trade name "Versed," which was not in the drug list of the medication dispensing system.

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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 submitted via Editorial Manager on the APSF website: https://www.editorialmanager.com/apsf
2. Please include a title page, which includes the submission's title, authors' full name, affiliations, conflicts of interest statement for each author, and 3–5 keywords suitable for indexing. Please include word count on the title page (not including references).
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Types of articles include (1) review articles, Pro/Con Debates and Editorials, (2) Q and As, (3) Letters to the Editor, (4) Rapid Response, and (5) Conference reports.

1. Review articles, invited Pro/Con debates, and Editorials are original manuscripts. They should focus on patient safety issues and have appropriate referencing. The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.
2. Q&A articles are submitted by readers regarding anesthesia patient safety questions to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.
3. Letters to the editor are welcome and should be limited to 500 words. Please include references when appropriate.
4. *Rapid Response* (to questions from readers), formerly known as, "Dear SIRS," which was the "Safety Information Response System," is a column that allows for expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. 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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# Position Statement on Criminalization of Medical Error (Cont'd)

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While the APSF focuses on perioperative safety, the issues addressed here apply to all health care delivery. In addition, the APSF will take action to reduce medication errors and to advocate and support those health care professionals who are treated unfairly when they have acted in good faith in caring for their patients.

**Why does the APSF believe this criminal prosecution was unjust and counterproductive?**

Based on the facts that have been reported, this most recent case represents how a combination of system and human failures combine to cause a tragic outcome. While the health care professional's responsibility for her role in this event may require education, monitoring of medication management competencies and discipline, her prosecution does not align with principles of "just culture" that are now widely accepted and improve health care.[6,7] This prosecution may lead to greater risk for patients when health care professionals' fear of significant retribution causes errors to go unreported and unaddressed, thus allowing the unidentified error to continue to harm more patients in the future.

Criminal prosecution provides no comprehensive mechanism for exploring the underlying causes of patient harm, including policy failures, implementation hurdles, or the impact of human factors to mitigate the risk of future error. There are no criminal mechanisms for health care to gather best practices, develop consensus statements, ideate, innovate, or deliver meaningful policy recommendations. Organizations, institutions, and individual health care professionals must instead work together to solve complex and often challenging medical issues to assure the safety of systems of care for patient best outcomes and safety.

**This type of criminal prosecution of health care professionals is fortunately very unusual and rare:**

It is rare for health care professionals to be criminally prosecuted for errors, and there is no indication the Tennessee case is representative of a trend. Specifically, the anesthesia data we have suggests that there are almost no events, with the few exceptions of truly egregious actions or inactions. Yet, many health care professionals have voiced concern that they may be similarly prosecuted for actions they have taken in good faith that led to an adverse outcome in part as a result of their error. This understandable fear could lead to health care professionals leaving the profession or failing to report errors as needed to identify and address causes of error and possible patient harm.

**Why is the APSF speaking out about this now?**

Numerous health care organizations concerned about patient safety have spoken out about the injustice, unfairness, and harm caused by criminalization of medical errors. The APSF is adding its voice to this issue because of its history of advocacy for patient safety. More importantly, the APSF is going beyond criticism of the prosecution of this nurse. What is equally and more important about this event is that it illustrates the harm that is being done far too often by faulty systems of care.

The APSF was founded during a time when the focus of attention on adverse outcomes was generally to pursue tort reform to prevent unreasonable malpractice awards. Dr. Ellison C. Pierce, Jr., as President of the American Society of Anesthesiologists in 1984, took the path of calling for prevention of errors that cause adverse events as the major focus for action. Dr. Pierce was the driving force behind the creation of the APSF. We are, via this position statement, continuing in that mission by calling on actions to promote patient safety and prevent errors as the way to prevent criminalization of medical error.

If the prosecution of the nurse in this case were to prompt copycat prosecutions, that would pose a grave danger to patient safety. Equally, if not more important, this case illustrates how serious errors and adverse outcomes continue to occur and that there does not yet appear to be a nationwide safe and just culture among health care institutions that fosters reporting of poor systems of care, near misses, or errors to prevent future error and patient harm. For that reason, the APSF is urging that cases like this never be pursued by prosecutors, who should have the best interests of patients and society at heart. And we are calling to action all stakeholders to proactively assess their systems of care to identify and prevent similar events from happening across all health care settings.

**When is it appropriate to prosecute health care professionals for errors?**

We acknowledge that there are some instances where criminal prosecution may be warranted, such as when a health care professional engages in a pattern of reckless behavior in providing care, commits errors that lead to harm while under the influence of substances that impair performance, or intends to harm (by definition, this is not an "error").

**What health care organizations must do to prevent errors and acknowledge those that do occur:**

The type of event that occurred in Tennessee is not unique among health care organizations. Despite the many successful efforts by some organizations to address patient safety issues, there is still an egregious rate of preventable harm in health care that has been hampered by a failure of all stakeholders to work collaboratively and aggressively to innovate to ensure that safety procedures, technologies, and practices are widely deployed and continuously improved. To advance patient safety, the APSF believes that health care systems and health care professionals should:

- Ensure patients and family are treated with compassion and transparency.
- Disclose to the appropriate authority (e.g., local or state) when harm resulted during the delivery of care.
- Operate on the principles of a "Just Culture" and "Culture of Safety." [6,8]
- Employ medication safety techniques and technologies that prevent the types of errors represented in the case in Tennessee and others nationwide. These technologies force safe function and mitigate errors contributed by human factors, and include the following:
  - Use prefilled syringes when possible.
  - The use of barcode/RFID technology for removal of medications from an automated dispensing cabinet (ADC).
  - Develop a multidisciplinary medication safety committee that meets regularly to evaluate all safety threats in your system.
  - Create a culture, reflected in policy, where all providers have a defined mechanism to report near misses and medication errors and are encouraged to speak up without fear of retaliation and provide actionable change when patient safety threats are observed. This culture change may involve having a medication safety officer who assists providers in difficult situations involving medication administration.
- Review and consider for implementation the items in the plan of correction[9] submitted by the organization involved in this event with special attention to
  - transport policies
  - communication during vulnerable handoffs .

**What can/should health care professionals do now to combat medication error and failure to monitor, and improve their organization's safety culture?**

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# Anesthesia Professionals Should Take Action to Combat Medication Error and Failure to Monitor

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- Take action in your organization to identify and address the types of system flaws that were exposed in the case in Tennessee to prevent error.[3] These might include
  - Evaluate medication dispensing methods for high-risk drugs, e.g., generic vs. brand name, therapeutic area and location of use, and consider evaluation of current workflow to enhance safety checks prior to medication administration.
  - Only use a medication dispensing override when required in urgent or emergent situations.[10]
  - Except in case of emergency, institute double medication verification systems for all override pathways when removing medication from automated dispensing cabinets.
  - Ensure appropriate monitoring of patients receiving high-alert medications
  - Deter a culture where "normalization of deviance" and the associated practices occur.[5]
  - Empower others and yourself to report actions that may put patients at risk and remediate those actions.[7]

## APSF POLICY ON CRIMINALIZATION OF MEDICAL ERROR

**What the APSF will do if a perioperative professional is prosecuted for an error unjustly:**

- Learn as much as possible about the circumstances of that event.
- If warranted, provide information to a prosecutor about system issues and the harm that would be done by prosecuting a health care professional who intended no harm and had helpful intent.
- Make public statements about the harm of unreasonable retribution for medical error reporting to patient safety in prosecuting health care professionals.
- Provide comfort to the health care professional.

**What the APSF will do to foster patient safety prompted by events such as this recent one:**

- Make public statements about efforts by organizations and government agencies to improve patient safety, specifically medication error, which is still being given too little focus based on its frequency and the continued extent of injuries.
- Make best practices available to all health care practices and professionals that can be used to reduce medical error.
- Make information available to patients so they can actively contribute to and monitor their care plan to optimize safety.
- Work collaboratively with professional organizations and advocacy groups to enhance awareness of the problem of medical errors and system failures that lead to adverse events to identify and implement best solutions.
- Continue to convene consensus processes for recommendations on medication safety.

The APSF believes that national, state, and facility policy should hold leadership and health care providers responsible for continuous systems of care evaluation and improvement to minimize risk of patient harm due to error. One opportunity to leverage policy across health care organizations is the Centers for Medicaid and Medicare Services Conditions of Participation, which include safety requirements in each chapter.[11] Those requirements provide accrediting organizations with a framework to continuously evaluate facility safety practices to demand improvement when necessary and to share nationally best practices as they emerge.

The APSF will take a collaborative approach with multiple stakeholders including health care professionals, health care organizations, professional societies, policymakers, manufacturers, technology companies, legal professionals, and government agencies to foster the highest level of patient safety and to prevent errors that subsequently result in patient harm.

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# Anesthesia Professionals Must Take Action to Eliminate "Normalization of Deviance"

From "Editorial: Criminalization," Page 78

Ms. Vaught, who was mentoring a student that day, did not routinely administer midazolam. She did not know that Versed and midazolam are the same medication, and she could not find it in the automated medication dispensing cabinet. She used the override function that led to her picking up a vial of vecuronium, which was the first listed drug and coincidentally had the same first two letters "VE" as Versed. It was common for nurses to override warnings; doing otherwise would often make care impossible, especially in emergency situations. Thus, nurse Vaught retrieved vecuronium and, for whatever reason, did not read the label and warnings about its paralytic properties. In addition, she did not realize that vecuronium required reconstitution with a solvent and midazolam did not. Because the MRI Department did not yet have bar coding scanning in place, her usual practice of doing so was not executed. Having other assignments in the Emergency Department with her student, she left the patient with a radiology technician who took her to a holding area where she was left unmonitored. The outcome of this action needs no explanation to an anesthesiology audience.[2]

The health care organization privately paid an undisclosed sum to the family as compensation, with agreement that the family remain silent. The organization did not report the event, as required, to regulatory bodies. It was almost a year later, through a whistleblower, that the event became known to regulators, after which action was taken, including the beginning of prosecution of the nurse.[4]

This event came more into the public eye when the prosecution began in 2022. In response, Dan Cole, MD, president of APSF, convened a multidisciplinary task force that was charged to develop an APSF position statement and policy for action for similar future events. The members of the task force included a leader of a patient advocacy organization, health care providers (anesthesiologists, CRNA, pharmacist, and surgeon), risk management professional, lawyer, and biomedical engineer/patient safety leader. Immediately upon starting its work, the task force decided that the focus should be more on prevention of future harm by instituting safer practices immediately as well as developing new ones. As noted in the position paper, this is in the founding spirit of APSF. Under the leadership of its founding President, Ellison C. Pierce, Jr., MD, APSF sought to prevent adverse outcomes as the means to address the crisis in rising malpractice payouts. Given that success, the natural path to obviating prosecution of well-intentioned health care providers, as well as protecting them from becoming second victims, should be to create and implement actions that make it nearly impossible to cause harm to patients from preventable causes.

We, on the task force, recognized that the nurse has culpability and that in such cases, disciplinary and other actions may be warranted. Yet, we explain in the position paper why we feel criminalization of medical error is unjust and counterproductive and why APSF is addressing this issue now. We call health care organizations to act now with specific suggestions to prevent errors and acknowledge those that do occur. We advocate for actions that health care professionals can take now to combat medication error and failure to monitor and improve their organization's safety culture. We hope that health care organizations will support a "Just Culture," where prevention of harm is the focus, and where managers and health care providers are encouraged to design safety systems and make safe choices for patient care.[4] Lastly, we state what APSF will do to support perioperative professionals should they be prosecuted unjustly and how APSF will foster patient safety prompted by events such as this recent case.

We hope all readers of this *Newsletter* will take the time to learn lessons from this tragedy so that we collectively honor Ms. Murphey and all patients who are harmed by adverse events whether in perioperative care or anywhere during their health care experience. Ask questions of and push your own hospital, department, and yourself to do what is possible to apply best current safety practices and encourage a culture of safety. Please become part of that effort; if you already are, amplify your activities. Collectively, we can make a difference.

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*None of the authors have conflicts of interest related to this article.*

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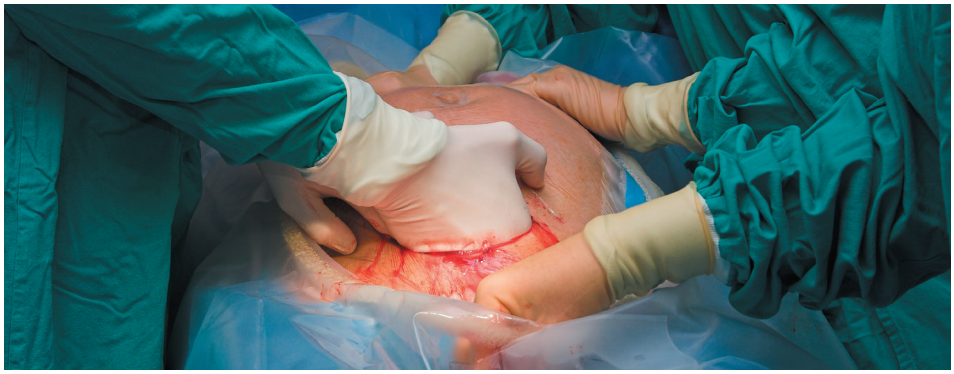
# Recognition and Management of Amniotic Fluid Embolism: A Critical Role for Anesthesia Professionals on Labor and Delivery

*by David E Arnolds, MD, PhD*

Amniotic fluid embolism (AFE) is a catastrophic complication unique to the obstetric patient characterized by acute cardiovascular collapse and a profound coagulopathy.[1] While AFE is rare, with an incidence of 1–2/100,000 pregnancies, it is associated with a mortality or permanent neurologic injury rate of 30–40%.[1,2] AFE is the second leading cause of maternal death on the day of delivery in the United States.[3] Early recognition and goal-directed treatment of suspected AFE is critical to successful management and decreasing morbidity. Women who die of AFE are less likely than those who survive to have an obstetrician or anesthesia professional present at the time of AFE,[2] highlighting the critical role for early recognition. Despite being recognized as a syndrome for nearly 100 years, the etiology of AFE remains elusive, the diagnosis remains clinical, and management is entirely supportive. The goal of this article is to review the presentation, differential, and initial management of AFE as well as to discuss potential avenues to further our understanding and management of this rare, but potentially fatal syndrome. Given the critical need for timely and focused intervention for AFE, the development of facility-specific cognitive aids is recommended to assist in initial management.[4]

The historical lack of consistent criteria for diagnosing AFE has made it challenging to define the true incidence of the syndrome and has hampered efforts to evaluate treatment strategies. AFE is a clinical diagnosis based on cardiorespiratory collapse and coagulopathy in the absence of other conditions sufficient to explain these symptoms: there are no serum or histologic findings specific to AFE. The need to rely on clinical criteria has likely resulted in both over- and underdiagnosis, with underdiagnosis of mild cases as well as inappropriate diagnosis of AFE in women who become critically ill from other causes. Given that AFE is considered the least preventable cause of maternal mortality,[5] there may be additional medical legal pressure to diagnose AFE in some cases of maternal mortality. Furthermore, international criteria for diagnosis of AFE vary considerably,[2] and some definitions include the presence of fetal epithelial cells in post-mortem histopathologic samples from maternal lungs, despite evidence that the presence of fetal epithelial cells in the maternal pulmonary circulation is neither specific nor sensitive for AFE.[6,7] In an effort to standardize diagnosis and reporting of AFE for research purposes, an expert panel convened by the Society for Maternal-Fetal Medicine and the Amniotic Fluid Embolism Foundation has proposed diagnostic criteria (commonly referred to as the Clark Criteria) for amniotic fluid embolism for research purposes (Table 1).[8]



AFE must be distinguished from other life-threatening causes of cardiovascular collapse in obstetric patients. In an analysis of cases submitted to the United States AFE Registry, obstetric hemorrhage was the most common actual diagnosis in cases misdiagnosed as AFE.[9] While severe obstetric hemorrhage may cause life-threatening hypotension and hemostatic derangements, it can be distinguished from AFE by both the antecedent event as well as by the absence of respiratory compromise. Sepsis is associated with hypotension and can cause both hypoxia and a coagulopathy, but typically is insidious in onset and is associated with maternal hyper- or hypothermia. Anaphylaxis can cause hypotension and hypoxia, but is not associated with a coagulopathy and occurs in association with exposure to an allergen, such as a medication, latex, or chlorhexidine skin prep. Anesthetic complications, such as a high neuraxial block, can be associated with hypotension and respiratory compromise, but do not include a coagulopathy and can further be distinguished from AFE by the association with neuraxial anesthesia. While pulmonary venous or air embolism can cause hypotension and hypoxia, they are not typically associated with a coagulopathy. Similarly, hemodynamic collapse from a primary cardiac etiology, such as an acute myocardial infarction, does not present with a coagulopathy and typically occurs in the clinical context of patients with known risk factors or recognized cardiac pathology.

The criteria described in Table 1 are biased towards specificity as opposed to sensitivity and thus some cases of AFE may not meet these strict criteria. A slightly more liberal definition was agreed on through a Delphi process by an expert panel assembled by the International Network of Obstetric Surveillance Systems (INOSS): acute cardiorespiratory collapse within 6 hours after labor, delivery or ruptured membranes, with no other identifiable cause, followed by acute coagulopathy in those women who survive the initial event.[10] In an analysis of cases submitted to the United States AFE registry, 12% of cases were considered atypical in that they did not meet the full research criteria, but nevertheless were felt upon expert review to represent AFE.[9] In contrast, the INOSS found that 31% of cases[2] collected by member institutions met INOSS, but not Clark Criteria, with a lack of evidence for DIC being the most common reason for not meeting the Clark Criteria. At a practical level, while obtaining laboratory studies to assess coagulation status can be essential in the management of a critically ill patient, it may not occur, or may not occur in the appropriate time frame, in the context of ongoing resuscitation.

Some patients with AFE will present with cardiac arrest as their first recognized symptom: for these patients, initial management should focus

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**Table 1: Diagnostic Criteria for Research Reporting of Amniotic Fluid Embolism.[8]**

1. Sudden onset of cardiorespiratory arrest, or both hypotension (systolic blood pressure <90 mm Hg) and respiratory compromise (dyspnea, cyanosis, or peripheral capillary oxygen saturation [$SpO_2$ < 90%).
2. Overt disseminated intravascular coagulation (DIC)* following appearance of these initial signs or symptoms. Coagulopathy must be detected prior to loss of sufficient blood to itself account for dilutional or shock-related consumptive coagulopathy.
3. Clinical onset during labor or within 30 min. of delivery of placenta
4. No fever (>38° C) during labor

*A score >3 is considered compatible with overt DIC in pregnancy

**Platelet count** >100,000/mL = 0, <100,000/mL = 1, <50,000/mL = 2

**Prolonged prothrombin time or international normalized ratio (from baseline):** <25% increase = 0, 25–50% increase = 1, >50% increase = 2

**Fibrinogen level:** >200 mg/dL = 0, <200 mg/dL = 1

# Amniotic Fluid Embolism (Cont'd)

From "Amniotic Fluid Embolism," Preceding Page

on providing high-quality advanced cardiac life support as outlined in the American Heart Association Scientific Statement on Cardiac Arrest in Pregnancy.[11] Key considerations in pregnant patients of greater than 20 weeks of gestational age include left uterine displacement, prioritization of oxygenation and airway management, and perimortem cesarean delivery (resuscitative hysterotomy) to relieve aortocaval compression and aid in maternal resuscitation within 5 minutes of arrest if return of spontaneous circulation (ROSC) has not been achieved, regardless of fetal viability. For patients with AFE who do not present with cardiac arrest or in whom ROSC is achieved, acute pulmonary hypertension and right ventricular failure is typically the primary initial presentation.[12] Right ventricular failure may progress to left ventricular failure with ongoing clinical deterioration. Focused cardiac ultrasound (either transthoracic or transesophageal) is within the scope of appropriately trained anesthesia professionals, provides valuable diagnostic information, and can be used to guide therapy.[13,14] Norepinephrine or epinephrine may be appropriate depending on the extent of circulatory collapse, with consideration for use of dobutamine or milrinone for inotropic support and inhaled nitric oxide or epoprostanol as pulmonary vasodilators.[4,12] As these agents are not routinely available on most labor and delivery units, phenylephrine and epinephrine may be appropriate in the initial phases of resuscitation, and the locations of, and processes to rapidly obtain advanced inotropic support and pulmonary vasodilators should be identified in institutional-specific planning sessions and clearly featured on cognitive aids. Similarly, extracorporeal membrane oxygenation (ECMO) can be considered early if it is institutionally available, and cognitive aids should include ECMO contact information. Overzealous fluid administration should be avoided in the presence of right ventricular failure.

Patients who survive the initial cardiorespiratory collapse associated with AFE go on to develop a profound coagulopathy. Viscoelastic testing may help guide rational management of blood products and clotting factor concentrates,[15] although empiric ratio-based resuscitation may be necessary in the face of massive ongoing hemodynamically significant hemorrhage. Several case reports and case series suggest hyperfibrinolysis during AFE,[16,17] and tranexamic acid administration (1 g IV over 10 minutes, with the possibility of an additional 1g dose after 30 minutes with ongoing bleeding) is recommended[4] based on extrapolation from the WOMAN trial[18] despite the lack of specific evidence for efficacy in AFE. Administration of a concentrated source of fibrinogen (fibrinogen concentrate or cryoprecipitate) has also been associated with improved outcomes,[2] consistent with the established role for treating hypofibrinogenemia in obstetric hemorrhage. Uterine atony should be anticipated and prophylactically treated to further limit blood loss following delivery.

While multiple "treatments" for amniotic fluid embolism have been proposed in case reports or suggested in discussions of the syndrome, none have been universally accepted or are supported by evidence. Proposed treatments include hydrocortisone,[19] lipid emulsion,[20] C1 esterase inhibitor,[21] and the combination of atropine, ondansetron, and ketorolac, often referred to as "A-OK."[22,23] While hydrocortisone is effective in the treatment of adrenal insufficiency and plays a role in managing allergic reactions, lipid emulsion is effective for local anesthetic systemic toxicity, and C1 esterase inhibitor is effective for treatment and prevention of hereditary angioedema, there is no evidence supporting use of any of these agents to treat AFE. Similarly, atropine is an effective antidote in cases of cholinergic poisoning, but there is no evidence for the effectiveness of atropine, ondansetron, and ketorolac in treatment of AFE. Unless or until additional research demonstrates the effectiveness of any case-reported treatments for AFE, they should not distract from prioritizing effective supportive care.

AFE is a rare and potentially catastrophic event. As with all such events, postevent debriefing sessions are crucial to offer support to affected staff members and identify opportunities for improvement. In addition, contacting the Amniotic Fluid Embolism Foundation (https://afesupport.org/) for all suspected cases is recommended as it provides an additional source of support for the patient and their family. Furthermore, the AFE Foundation supports a registry and biorepository that facilitates research on this rare syndrome with the goal of transforming AFE into a predictable, preventable, and treatable condition. Until such advances occur, early recognition and high-quality supportive care are essential to decrease the morbidity from AFE.

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*The author has no conflicts of interest.*

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RAPID Response
to questions from readers

# Transportation of Pediatric Patients With Hyperinflation System

*by James Xie, MD and Jonathan Barnett, MD*

**Dear Rapid Response:**

Transporting patients is a high-risk process, accounting for up to 5% of pediatric anesthesia adverse events.[1] Studies have identified respiratory and airway adverse events as some of the most common complications, along with the role of transport equipment in reducing risk.[2] The role of equipment in safe patient transport highlights the importance of human factors engineering in the design of medical devices utilized by health care providers. Human factors engineering considers the capabilities and limitations of humans and addresses the interface design of equipment to promote safe, reliable, and efficient use in various situations.[3,4] Using a human factors perspective, we would like to describe the design of a pressure valve found on the SunMed Ventlab HS4000 Series Hyperinflation System (Figure 1, Figure 2, Ref. HS4011, Ventlab, LLC; Grand Rapids, MI). This product temporarily replaced our existing Jackson-Rees transport circuits due to supply shortages at our institution.

The SunMed Ventlab Hyperinflation System includes a color-coded pressure manometer and a pressure adjustment valve. The manufacturer describes the valve as a "stay-put dial" to set a static pressure. However, our institution's health care providers found the interface for adjusting the dial counterintuitive: increasing pressure requires counter-clockwise rotation, and decreasing pressure requires clockwise rotation. Our perioperative staff found this design to be atypical compared to all other hyperinflation devices used in our hospital. The familiar adage "righty-tighty, lefty-loosey" that helps guide people to rotate right, or clockwise, to tighten an apparatus and left, or counter-clockwise, to loosen does not apply in this device's design. Furthermore, the dial is made of white plastic with a label indicating the direction of turn that is difficult to read due to lack of color contrast (Figure 1, right panel). The counterintuitive design of the dial confused providers during patient transport, which had the potential for delayed care, specifically in a critical scenario where effective positive pressure ventilation is required. Realizing this design difference, rapid education was conducted with perioperative care providers using this hyperinflation system.

For anesthesia professionals especially, a comparison can be drawn between the pressure dial on the hyperinflation system and the adjustable pressure-limiting (APL) valve on anesthesia machines. The International Organization for Standardization (ISO) has standards that apply to the design of all APL valves on anesthesia machines. In regulatory standard ISO 80601-2-13:2011, exhaust valves, which include APL valves, should have their pressure adjusted such that clockwise rotation closes the valve and increases circuit pressure, and counter-clockwise rotation opens the valve and decreases the pressure.[5] In other words, "righty-tighty, lefty-loosey." The APL valve is used day-in and day-out by anesthesia professionals. Thus, when encountering another flow-dependent oxygen delivery device with a valve, anesthesia professionals are likely to attempt to turn a valve clockwise in order to close it to increase pressure delivered to the patient based on their familiarity with this standard.

Given ongoing supply chain challenges, providers often face substitute devices that may not be equivalent to the device they are accustomed to using. Furthermore, supply chain managers should work closely with clinicians to ensure that design differences that may have patient safety implications are addressed when making substitutions. In the case of the SunMed Ventlab Hyperinfla-

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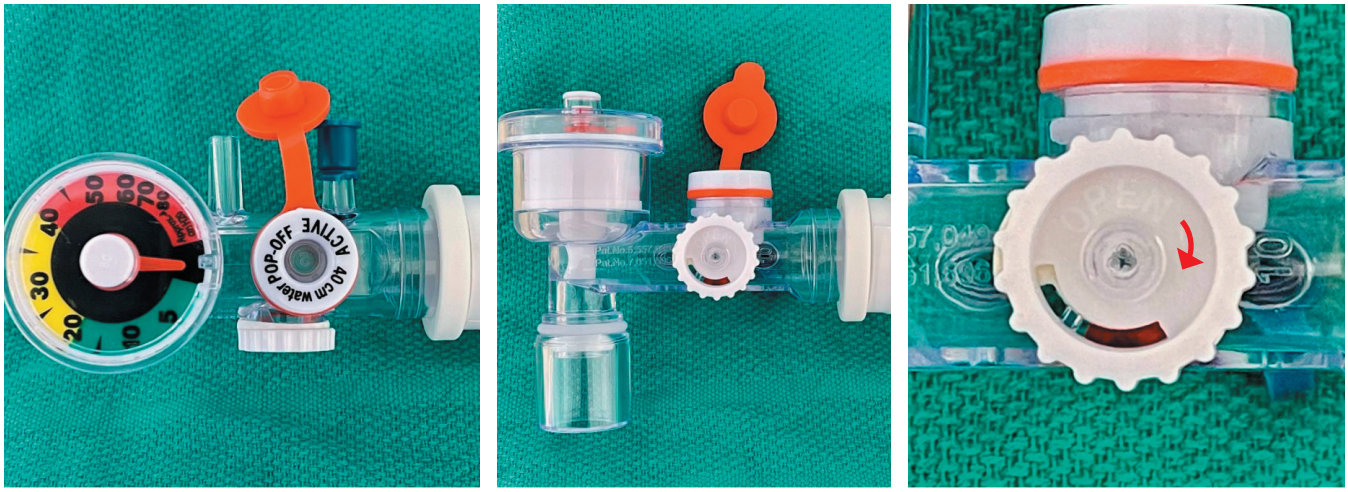


*Figure 1: Multiple views of the SunMed Ventlab Hyperinflation System (Ref. HS4011, Ventlab, LLC, Grand Rapids, MI) with attention to the Adjustable Pressure Valve. Note that the white text on white plastic is difficult to read. The clockwise arrow is labeled "Open"—which is the opposite of what is typically expected (where clockwise rotation usually leads to closure of a valve).*

RAPID Response
to questions from readers

# Transportation of Pediatric Patients with Hyperinflation System (Cont'd)

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tion System, the dial design is opposite to the commonly available design of the Mapleson circuits that were routinely used at our institution. This counterintuitive design is a potential patient safety issue, and clinicians should be aware of this limitation if faced with these devices. In this time of disrupted supply chains, there is often little lead time to maintain desired inventory, but as much as possible, supply chain managers should confirm that a product is clinically acceptable before making a substitution. Furthermore, appropriate in-service education may help mitigate potential issues from arising from use of unfamiliar substitute devices.

Thank you for your concern and attention to this matter.

*James Xie, MD*
*Jonathan Barnett, MD*

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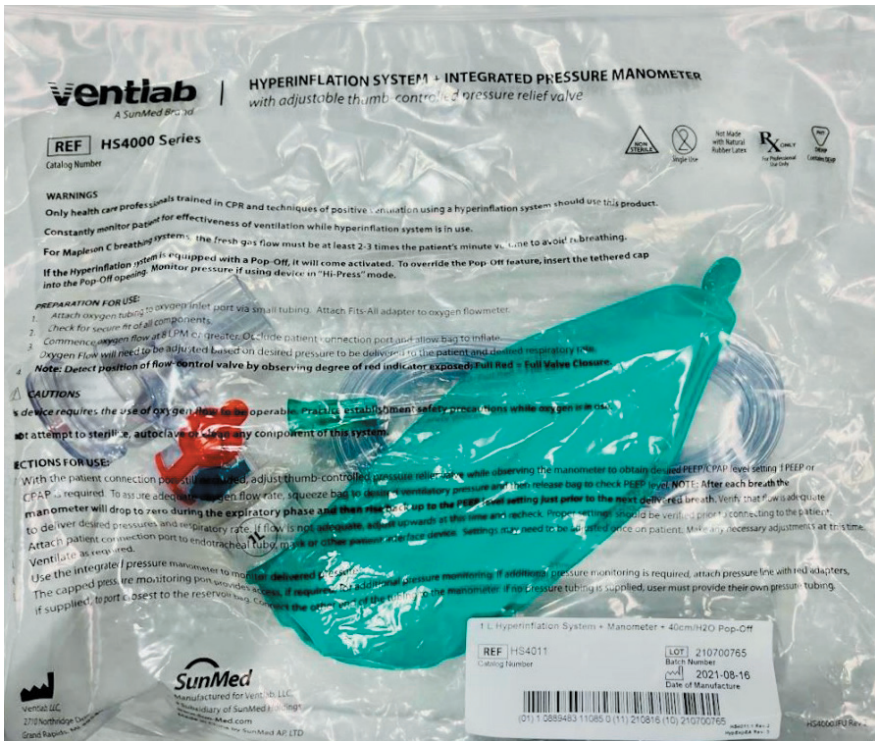


*Figure 2: Full packaging of the SunMed Ventlab Hyperinflation System (Ref. HS4011, Ventlab, LLC; Grand Rapids, MI).*

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RAPID Response
to questions from readers

# MANUFACTURER RESPONSE: Transportation of Pediatric Patients with Hyperinflation System

From "Rapid Response," Preceding Page

**Dear Rapid Response:**

We appreciate the opportunity to respond to the article on the Ventlab HS4000 series hyperinflation system with integrated manometer and pop-off, one of the most widely used hyperinflation systems in the market today.

When introducing customers to new products, SunMed believes education is key. It is important for clinicians to be educated on products prior to use as devices may have different features. Different, however, does not mean counterintuitive when performance features are understood.

**SunMed provides:**

- Comprehensive Instructions for Use
- Training and education
- In-service support for conversions across our breadth of products

Education includes how to control and interpret the pressure relief valve. The valve within the hyperinflation system does not contain an APL (adjustable pressure-limiting) valve as the report makes comparison to, and therefore, is not intended to function similarly. Instead, the Ventlab Hyperinflation System device functions like most frequently used hyperinflation systems on the market and comes with a pressure relief valve that rotates forward, closing the valve and restricting flow (increasing pressure), or inversely, rotates backwards, opening the valve (reducing pressure). The pressure relief valve located on the side of the device was designed by a clinician with consideration for human factors and ease of use. The valve allows for one-handed adjustment with the thumb during use, while continuously monitoring the pressure on the integrated manometer and/or the patient. Additionally, the valve comes with a visual aid to leverage the benefits of visual indication through a red indicator window which provides added ease-of-use when identifying the position of the valve (full red = fully closed, no red = fully open) prior to and during utilization.

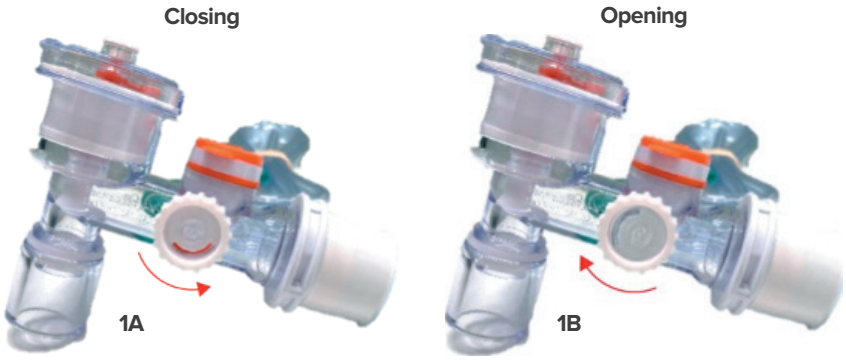


*Figure 1: The Ventlab Hyperinflation System device comes with a pressure relief valve that rotates forward (1A) closing the valve and also rotates backward, thereby opening the valve (1B) and reducing pressure.*

SunMed thanks the authors for sharing this report and for the feedback which is welcomed as part of our culture for continuous improvement. SunMed also appreciates the opportunity to discuss the clinical design benefits of the Ventlab Hyperinflation System and the critical importance of product training.

*Sincerely,*

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*The authors have no conflicts.*

# Can Nudges Mitigate Deadly User Errors?

*by Molly Kraus, MD, and Karl Poterack, MD*

In May of 2022, a former Vanderbilt nurse was convicted of gross neglect of an impaired adult and criminally negligent homicide for the death of her patient in 2017. While she had intended to give her patient midazolam (Versed) for sedation during a radiologic procedure, she inadvertently administered a fatal dose of the neuromuscular blocking agent vecuronium. She overrode safety features on the automated medication dispenser (AMD) and failed to catch several red flags between the time she searched the dispenser for the medication and administered it to the patient.[1]

This case captivated much of the health care industry in the United States. The American Nurses Association released a statement warning that the trial could create a precedent that would ultimately endanger patients if the criminalization of medical errors has "a chilling effect on reporting and process improvement."[1]

In her testimony, the accused nurse said that the use of overrides on the automated medication dispenser were common at Vanderbilt at that time. Reports suggest that the hospital had recently updated the electronic health record system, which had caused delays at AMDs.[2] Testimony included statements that Vanderbilt instructed nurses to use overrides to circumvent delays and get medicine as needed, the nurse stating to the nursing board that, "you couldn't get a bag of fluids for a patient without using an override function."[2]

In this case, several incentives, pressures, and nudges are evident. From the public record, we gather there was an expectation that the nurse involved would "multitask" by orienting a new hire as she was caring for this patient.[3] It seems production pressure may have been present, as the nurse involved was reportedly told that the patient would have to be sent back and rescheduled if the sedation wasn't given soon, perhaps implying to the nurse that she was not moving fast enough.[4] There was also no "sterile area" around the AMD for medication removal; this has become a standard in many institutions to minimize distractions while removing/handling medications.[3,5]

In Thayer and Sunstein's 2008 best-selling book, "Nudge: Improving Decisions about Health, Wealth and Happiness," they introduce how nudges influence behavior without coercion.[6] "Nudging" is defined as a "function of any attempt at influencing people's judgment, choice, or behavior in a predictable way, that is made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making." [6] Nudge strategies are currently used in multiple ways in the medical field. The University of Pennsylvania Health System even has a dedicated nudge team whose mission it is to improve health care delivery with nudges.[7] Specific types of nudges include cues, priming, default settings/options, establishing norms, and prompting. The digital transformation of health care, including electronic health records (EHR), electronic medication dispensing systems, and electronic anesthesia records, lends itself to many possibilities for behavioral nudges.

There were a few "nudges" present in the Tennessee case intended to reduce the risk of medication error: there was a warning label on the top of the vecuronium vial alerting that it was a paralyzing agent, as well as a need to dilute the medication (which would not hold true if it were midazolam). However, there were several "potential" nudges that were lacking. The AMD was set up to allow medications, in this case neuromuscular blocking agents, to be available on a med/surg nursing floor even when not routinely ordered. A nudge based on a safer practice would only allow ordered medications to be removed; a further nudge would even restrict certain medications such as neuromuscular blocking agents in locations where they are not in routine use.[3] The Institute for Safe Medication Practices recommends that neuromuscular blocking agents should not be stocked in areas such as med/surg floor where they are not routinely used, or if they are, they be included as part of "emergency intubation kits" with multiple warning signs.[3] Additionally, typing in "VE" on the unit produced the choice to remove vecuronium as well as "Versed;" again, a nudge that produced more relevant choices and fewer irrelevant ones would encourage safety. Finally, restricting the use of overrides to only necessary situations in a system like this is also a potential nudge. However, all necessary situations cannot be anticipated, a reality which necessitates having an override option for rare, unexpected cases. Nevertheless, overrides should never be a standard practice to obtain medications.

Nudge theory can be seen as part of a broad structure of incentives, expectations, and pressures, whether intentional or unintentional, that help shape activities and choices made by individuals. In the workplace setting (and elsewhere), people, to a great extent, behave in a way consistent with what they think is expected of them. This is often the basis for "production pressure" which is defined by Gaba et al. as "overt or covert pressures and incentives on personnel to place production, not safety, as their primary priority."[8] This will occur despite whatever leadership may say about safety, quality, etc., if the unspoken—and rewarded—expectation is that more work is done, faster.

A single nudge or even a series of nudges can help encourage people to make a choice that is more aligned with quality, safety, efficiency, or any other positive end. However, they can be "overwhelmed" by other incentives and pressures, intentional or not, that are present in the system. In addition, the absence of nudges in other key areas ("anti-nudges")—such as too-easy access to overrides on an AMD—can render meaningless the nudges that are present. The use of nudges needs to be a part of a comprehensive, intentional culture, in this case a comprehensive culture of patient safety.

An organizational culture, of course, is more than just a few decisions, nudges, or platitudes voiced here and there. A culture is built day by day, action by action, and moreover, it can be undone by a single lapse by leadership. A well-designed series of nudges to encourage patient safety, along with a campaign promoting safe care of the patient, will go for naught when there is a single high-profile instance of leadership valuing cost savings, or the appearance of efficiency, over patient safety.

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# "Nudges" Can Help Health Care Professionals Make Safer Choices

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Thus, as described elsewhere,[9] a series of well-designed nudges to encourage safe care of patients is an effective part of an overall culture that consistently values patient safety at all times. But even the most well-designed nudges cannot substitute for a strong culture of safety at an institution.

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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 2022. 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 Marjorie Stiegler, MD, our Director of Digital Strategy and Social Media at stiegler@apsf.org, Emily Methangkool, MD, the APSF Ambassador Program Director at methangkool@apsf.org, or Amy Pearson, Social Media Manager at pearson@apsf.org. *We look forward to seeing you online!*

*Marjorie Stiegler, MD, APSF Director of Digital Strategy and Social Media.*

# Risks and Benefits of the Use of the Postanesthesia Care Unit as an Intensive Care Unit and Special Considerations for Anesthesia Professionals

*by George Tewfik, MD, MBA, FASA, CPE, MSBA; Anupama Wadhwa, MBBS, MSc, FASA; Stephen Rivoli, DO, MPH, CPHQ, CPPS; and Patricia Fogarty Mack, MD, FASA*

## INTRODUCTION

The use of the postanesthesia care unit (PACU) for intensive care unit (ICU) overflow patients is a decision often made during times of high critical care bed utilization. In early Spring of 2020, the COVID-19 pandemic presented this challenge for hospitals overwhelmed with critically ill patients. The need for ICU-level care far exceeded existing capacity, and makeshift ICUs suddenly became the norm especially in U.S. geographic areas with exceedingly high concentrations of early viral outbreaks.

Some substitute ICUs were initially established in PACUs, where both physicians, nurses, and advanced practice providers are familiar with ventilator management. In the initial days of the COVID-19 pandemic, the immediate use of the PACU for ICU overflow was logical, given that elective surgeries were suspended and the capacity to accommodate overflow was readily available. General hospital floors and emergency rooms were also converted to ICUs, as the need for increased critical care units emerged. In extreme cases of bed demand, operating rooms were converted to ICUs, and the anesthesia machine was operationalized for ICU mechanical ventilation.[1] Though not an optimal solution, the rapid conversion of non-ICU units to functional ICUs was achieved with varying degrees of difficulty and success to accommodate patients requiring airway management and ventilator support. Additional modifications were made to PACUs to establish isolation rooms, such as putting up temporary partitions and building anterooms with HEPA filtration. While not universal, some operating rooms were converted from positive airflow pressure to negative pressure, which may reduce viral contamination.

When overflow patients hit regular floor beds, even more modifications were required to provide ICU-quality care. Fortunately, with the support of organizations such as the Army Corps of Engineers and local, state, and federal authorities, hospitals withstood the initial surges of COVID, and were left better equipped and experienced to handle future crises. These governmental associations contributed specialized medical equipment and clinical/logistic manpower, including nurses and physicians, while also setting up triage tents to manage emergency room overflows.

## PRE-PANDEMIC USE OF PACUs AS ICU OVERFLOW

Even before the pandemic, PACU beds have been utilized as overflow ICU space as hospital surgical volume and patient acuity increased.[2] For instance, the PACU has been utilized for overflow patients when the surgical intensive care unit (SICU) was filled to capacity.[2] In its traditional functionality as an overflow ICU, two types of critical care patients may be admitted to the PACU—those admitted directly from the operating room due to lack of SICU bed availability (overflow patients), and those brought to the PACU from SICU to free a bed for a more critically ill patient (e.g., patients on intra-aortic balloon pump or continuous renal replacement therapy).

The primary responsibility of a PACU is to provide an optimal standard of care for postanesthesia patients and to ensure that the surgical schedule is maintained by providing capacity for the operating room.[3] Thus, prior literature has advocated strongly against the use of the PACU as a solution to the shortage of critical care beds.[3] This is due to potential bed shortages in the PACU that may affect operating room functionality. In 2000, the American Society of PeriAnesthesia Nurses, American Association of Colleges of Nursing, and American Society of Anesthesiologists issued a joint statement regarding ICU overflow in the PACU, advocating for a multidisciplinary approach to address proper utilization of ICU beds and minimize the need for overflow locations.[3] Recent literature has advocated for utilization of PACUs as ICUs after careful consideration of the impact on three distinct groups—ICU overflow patients, postoperative patients regularly admitted to the PACU, and perioperative nursing personnel.[4]

The PACU has nonetheless emerged as a safe and effective alternative for critically ill patients as more surgical procedures moved to outpatient centers, and hospitals filled with more acute cases.[5] Without building additional units to accommodate ICU-level patients, hospital administrators have often sought to utilize the PACU for overflow, given the available space, advanced monitors, and essential equipment, as well as staff trained in the care of high-acuity patients.[5]

## ADVANTAGES OF USING PACU AS ICU

There are numerous potential benefits to using a PACU as an overflow ICU when required by clinical conditions. The PACU is in close geographic proximity to the operating room, facilitating use of the unit as overflow for a surgical ICU for patients in the immediate postoperative period. Often it is faster and less complicated to transfer a patient requiring surgical ICU-level care to the PACU than a potentially more distant, nonsurgical ICU. PACU nursing staff are also highly trained and skilled to manage one or more patients that are intubated, on ventilators, or require specialized care (e.g., vasopressor infusions, continuous veno-veno hemofiltration (CVVH), intra-aortic balloon pumps (IABP), and pulmonary artery catheter management). A retrospective case analysis of patients who were treated in the PACU overnight following aortic surgery demonstrated no excess mortality or morbidity in patients when compared with those treated in the ICU.[6]

## DISADVANTAGES OF USING PACU AS ICU

There are several reasons why routinely using a PACU for critical care patients can be detrimental to both patients and the functionality of the operating room. ICU physicians and advanced practice providers may not be readily available to the PACU, and PACU nurses may not be familiar or appropriately trained to manage all nuances of ICU care, especially if the patient would normally be admitted to a specialty ICU. The admission history and documentation workflow for an ICU patient may also differ significantly from that of a postoperative PACU patient.

PACU-critically ill patients may also use space and staff that are subsequently needed for postsurgical patients, and therefore, operating room efficiency and safety to other patients may be negatively impacted. This can lead to

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# Using The PACU for ICU Patients Requires a Multidisciplinary Approach to Evaluate Its Available Capacity and Resources

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delayed or cancelled surgery and a decrease in clinician and patient satisfaction.

PACU nursing expectations and abilities to adapt to a dramatic shift in patient care activities may also be a stressor that affects patient care.[7] PACU nurses describe distress and a sense of giving substandard care when interviewed as part of a clinical study to assess nursing attitudes regarding care of ICU patients in the PACU.[8] Given the complexity of ICU patients, it is likely that PACU length of stay would be longer than the typical postoperative patient. Patients and their families may also be confused as to who is primarily managing patient care in the PACU. PACU care is often delivered by anesthesia professionals[9] in collaboration with the surgical team. ICU patients are often primarily cared for by a critical care physician and a specialized multidisciplinary team—personnel that are often not consistently present in a PACU. This may lead to confusion when a family member or loved one is in the PACU, but covered by a physician team from a critical care unit.

## DIFFERENCES IN PACU VS. ICU INFRASTRUCTURE

The infrastructure of the PACU is fundamentally different than that of an ICU. ICUs may have space, beds, seating, and amenities for patients' families, while PACUs typically do not have these resources. PACUs have the potential to expose ambulatory patients to the sickest ICU patients. Finally, PACUs don't typically have the resources inpatient units do such as on-unit staffed satellite pharmacies, social/pastoral service points, and patient movement/positioning equipment.[9,10]

## RECOMMENDATIONS

Before utilizing the PACU for ICU patients, each institution must weigh the potential advantages and disadvantages, and consider each factor in the context of maximizing patient safety and efficient utilization of resources (Table 1). It is imperative that each institution evaluate its available capacity and resources, and reassess its needs daily. Once there is an adequate understanding of a hospital's capacity and needs, then hospital staff can move towards developing a plan for efficient deployment of resources and to consider the use of excess capacity in such units as the PACU.

Anesthesia professionals should be involved with discussions on how to best utilize the resources of a PACU, given our importance in managing these units and our need to ensure patient safety and operating room efficiency. Although routine use of PACUs for ICU-level-care in patients needing short-term postoperative ventilation is common in the U.S., the use of the PACU for routine ICU overflow is a practice that requires delineation of staff responsibilities and shifting of available resources.

Anesthesia professionals must ensure that this process occurs, in a manner that avoids negatively impacting the operating room or surgical schedule and maintains patient safety. There must be clear lines of communication to ensure that management of ICU patients is directed by the most well-trained clinical staff regardless of the patient's physical location. Appropriate levels of training for all nurses who will be expected to take care of these patients is paramount. Physical resources such as IV pumps, ventilators, and monitoring equipment should be readily available. Support staff, including respiratory therapists, nursing assistants, and transporters, may also benefit this patient population, when treated in the PACU.

**Table 1. Potential Advantages and Disadvantages to the Use of the PACU for Patients in Critical Condition.**

| Advantages | Disadvantages |
|---|---|
| Proximity to the operating room<br>Highly trained nursing staff<br>Available respiratory therapists and ventilators<br>Advanced equipment readily available<br>Use of an under-utilized critical care unit | Decrease in nursing availability for OR cases<br>Use of physical space reserved for OR cases<br>Limited availability of nursing to cover more than one patient<br>Potential misuse by services which prefer patients near OR<br>Potential cause for cancellation or delay of surgical cases<br>Unclear delineation of physician responsibility for patients<br>Potential need for additional training/ continuing education for nurses<br>Differences in documentation required for patients |

## CONCLUSION

The utilization of the PACU as an ICU may relieve the stress of facilities management, hospital administrators, and critical care physicians in times of ICU bed shortage. But, there are potential risks that may affect patients, physicians, nurses, advanced practice providers, and ancillary staff. Though emergency conditions may render its use necessary at times, careful thought and planning of PACU care for ICU patients should involve anesthesia professionals to potentially mitigate the adverse consequences to patients and operating room efficiency by deploying this valuable resource in a unique manner.

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*The authors have no conflicts of interest*

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# "That Which Is Old Is New Again": *APSF Newsletter* "In the Literature" Synopsis Summaries Reappear

*by John H. Eichhorn, MD*

When the *APSF Newsletter* Editorial Board recently considered the proposal to publish a column compiling summaries of current relevant literature regarding perioperative patient safety, I, the founding editor, who has been referred to as the "institutional memory" of the APSF, immediately supported the idea enthusiastically, noting that the original *Newsletter* created in 1986 included precisely that same concept, and the column then was called "From the Literature." Read the online article that can be found at https://www.apsf.org/article/that-which-is-old-is-new-again-apsf-newsletter-in-the-literature-synopsis-summaries-reappear/ for further historical perspective on the original "From the Literature" articles.

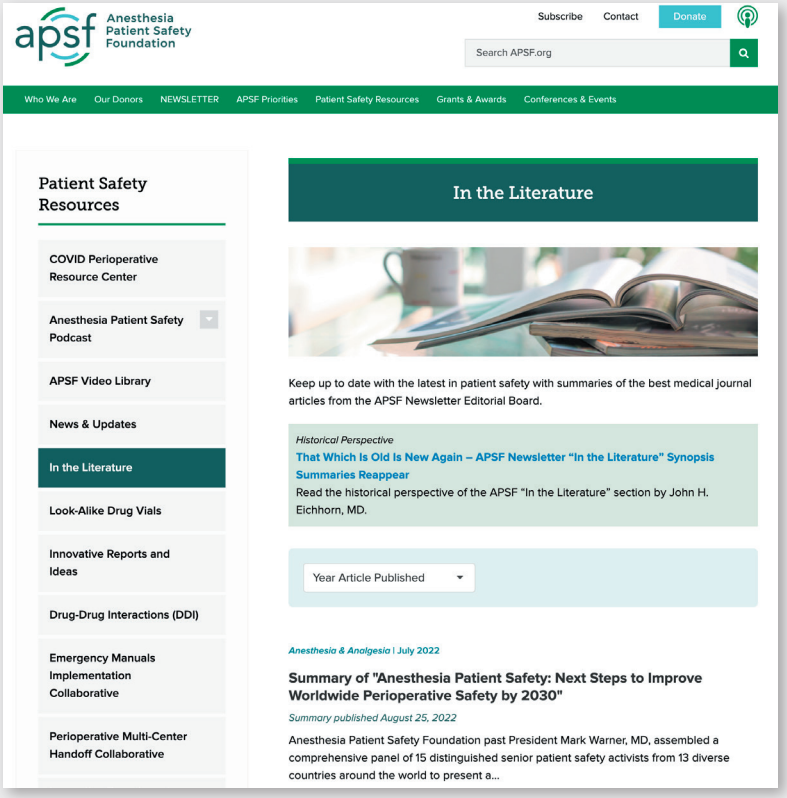
## REINCARNATION REALIZATION

An Editorial Board subcommittee has assumed responsibility for seeking out and presenting publications relevant to perioperative patient safety and potentially of interest to *Newsletter* readers by presenting summaries under the category "In the Literature." As the summaries are created, they first appear online on the APSF website (https://www.apsf.org/in-the-literature/) under the "Patient Safety Resources" section tab. The first presentation of these summaries appears in this issue of the *Newsletter*. The synopses cover a very wide variety of entries from different types of literature sources.

Several clinical questions are addressed in the articles summarized. A landmark paper in the *New England Journal* by Neuman et al. compared outcomes in those older adults undergoing spinal or general anesthesia for hip surgery. The study suggested that there was no significant difference in mortality or debility at 60 days postoperatively.[1] The authors concluded that spinal anesthesia was not superior to general anesthesia for hip fracture repair in this patient population.

In the article by Sencan S, et al. entitled, "The Immediate Adverse Events of Lumbar Interventional Pain Procedures in 4,209 Patients: An Observational Clinical Study," the safety of these blocks was affirmed in that no major adverse events occurred.[2]

Chen and colleagues compared a nasal mask and a traditional nasal cannula during intravenous anesthesia for gastroscopy procedures and the data suggested better oxygenation when using a nasal mask.[3]



https://www.apsf.org/in-the-literature/

Plans for extubation of difficult airways in pediatric patients are summarized in Weatherall AD, et al., "Developing an Extubation Strategy for the Difficult Pediatric Airway—Who, When, Why, Where, and How?."[4] Further, the elements of the most recent iteration of the ASA Difficult Airway Algorithm are outlined in a summary by Rosenblatt WH, et al.[5]

In Buis ML, et al., "The New European Resuscitation Council Guidelines on Newborn Resuscitation and Support of the Transition of Infants at Birth: An Educational Article," a comprehensive summary of the original publication is presented.[6]

The potential danger of provoking thromboembolism by synergistically mixing agents intended to reverse factor Xa inhibitor anticoagulants is discussed in: Liu J, et al. "Four-Factor Prothrombin Complex Concentrate Plus Andexanet Alfa for Reversal of Factor Xa Inhibitor-Associated Bleeding: Case Series."[7]

An important *JAMA* paper: Sun LY, et al. "Association Between Handover of Anesthesiology Care and 1-Year Mortality Among Adults Undergoing Cardiac Surgery," reported the finding of a statistically significant increase in morbidity and mortality when an intra-anesthetic handover occurred and offered recommendations for mitigation.[8]

One of the papers central to a currently discussed patient safety issue: Murphy GS, Brull SJ. "Quantitative Neuromuscular Monitoring and Postoperative Outcomes: A Narrative Review,"[9] presents a detailed review and analysis that supports routine adoption of quantitative neuromuscular monitoring for perioperative care.

The patient safety implications of anesthesia professionals' burnout during the COVID-19 pandemic are considered in: Lea J, et al. "Predictors of Burnout, Job Satisfaction, and Turnover Among CRNAs During COVID-19 Surging."[10]

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Three papers from British literature covering larger systemic questions are summarized. The value of implementing clinical guidelines is stressed in: Emond YEJJM, et al. "Increased Adherence to Perioperative Safety Guidelines Associated with Improved Patient Safety Outcomes: a Stepped-Wedge, Cluster-Randomised Multicentre Trial."[11] Application of artificial intelligence (AI) is highlighted in a summary: Sibbald M, et al. "Should Electronic Differential Diagnosis Support Be Used Early or Late in the Diagnostic Process?"[12] Also: Dave N, et al. "Interventions Targeted at Reducing Diagnostic Error: Systematic Review," covers several strategies, including, particularly, technology such as artificial intelligence.[13] Another aspect of that AI theme from a law journal: Kamensky S. "Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications," provides a corollary American perspective considering whether liability laws could apply to patients claiming injury from errors involving AI technology.[14]

The reappearance of literature summaries in the *APSF Newsletter* is a welcome addition to the panoply of valuable knowledge and insight continually presented for the benefit of our profession. As is the case with a great many, if not, in fact, most articles in the scientific/medical literature that conclude with the essential universal truth that "further research is indicated," so too is it analogous for these literature summaries. Readers are encouraged to forward suggestions of articles to be summarized or actual completed literature summaries to the *Newsletter* editors at any time.

*John H. Eichhorn, MD, was the founding editor and publisher of the* APSF Newsletter. *Living in San Jose, CA, as a retired professor of Anesthesiology, he continues to serve on the APSF Editorial Board.*

*John H. Eichhorn, MD*

*The author has no conflict of interest.*

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Professional titles and nomenclature were standardized and modified within the text consistent with APSF policy.

# Pro-Con Debate: Monitored Anesthesia Care Versus General Endotracheal Anesthesia for Endoscopic Retrograde Cholangiopancreatography

*by Luke S. Janik, MD, Samantha Stamper, MD, Jeffery S. Vender, MD, MCCM, and Christopher A. Troianos, MD, FASE, FASA*

In this Pro-Con commentary article, the authors have been asked to refute or support a position regarding anesthesia for endoscopic retrograde cholangiopancreatography (ERCP). ERCPs are unique in that they not only necessitate a shared airway but are typically performed in the prone (or semiprone) position on a special procedural table. Moreover, procedural times can vary from <1 hour to several hours.

The practice of medicine often varies among medical professionals when a defined standard of care does not exist. The cause of this variability is multifactorial. Patient factors and comorbidities, practitioner skills and experience, procedural needs, and the absence of data are a few of the considerations. Thus, it is not surprising that the primary mode of anesthesia for gastrointestinal (GI) endoscopy patients is sharply partitioned between those advocating for monitored anesthesia care (MAC) versus those who rely on general endotracheal anesthesia (GEA).

The importance of this debate is even more relevant because of the increasing recognition of significant potential morbidity and mortality associated with these anesthetics and procedures. A Closed Claims report from the American Society of Anesthesiologists (ASA) suggests that adverse events in nonoperating room anesthesia (NORA) sites result in a higher incidence of severe complications—including death and permanent brain damage—than similar events occurring in the operating room.[1] Indeed, the GI suite accounted for the highest percentage of adverse events across all NORA locations.

Anesthesia professionals will certainly encounter an increasing demand for services in the NORA setting and, especially, the GI suite. Thus, this Pro-Con debate provides insights into the care plan decision of MAC versus GEA for ERCP procedures, as summarized in Table 1. Our patients will ultimately benefit from further systematic clinical study of these variable approaches and their associated outcomes.

**Table 1: Pro-Con Debate Summary.**

| PRO side: arguments in favor of MAC for ERCP | CON side: arguments in favor of GEA for ERCP |
|---|---|
| No significant difference in overall serious adverse events when comparing MAC versus GEA in healthy, nonobese patients[2–4] | MAC is associated with unacceptably high rates of SRAEs (~20%), conversion to GEA (~3%), and hypoxemic episodes (~10%–30%)[4,6–10] |
| Avoidance of the potential problems associated with GEA including intubation-related injury, hemodynamic instability, and medication side effects | The only randomized controlled trial to date comparing GEA to MAC (in high-risk patients) demonstrated significantly higher rates of adverse events in the MAC cohort[10] |
| Improved gastrointestinal suite efficiency metrics and shorter patient recovery time[5] | NORA carries inherent risk, often related to impaired oxygenation and/or ventilation.[11] GEA provides a definitive airway. |
| Low conversion rate from MAC to GEA of <4%[4] | While MAC may be feasible for healthy, nonobese patients, in reality, these patients are few and far between. Patients presenting for ERCP are typically ill, often obese, and usually have multiple risk factors for SRAEs |
| Reliable detection of airway obstruction using end-tidal $CO_2$ monitoring and astute clinical observation, and rapid improvement with basic airway maneuvers | Efficiency metrics are unlikely to be improved by MAC—time saved is likely offset by interruptions for necessary airway interventions[12] |

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; GEA, general endotracheal anesthesia; MAC, monitored anesthesia care; NORA, nonoperating room anesthesia; SRAE, sedation-related adverse event.

## PRO: ANESTHESIA FOR ERCP IS BEST DONE WITH MAC

**Samantha Stamper, MD, and Christopher A. Troianos, MD, FASE, FASA**

ERCP utilizes fluoroscopy and endoscopy for both diagnostic and therapeutic interventions. Its use facilitates the evaluation of the liver, gallbladder, bile ducts, and pancreas. In recent years, ERCP has been predominantly used for therapeutic interventions given the advent of advanced endoscopy therapeutic techniques and imaging technology (eg, magnetic resonance imaging with magnetic resonance cholangiopancreatography, endoscopic ultrasound).[13] Such interventions include biliary sphincterotomy, gallstone extraction or fragmentation, biliary and pancreatic duct stenting, and pancreatic pseudocyst drainage.[12,13]

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# MAC vs. General Anesthesia for ERCP Procedures

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Many of these procedures previously required open or laparoscopic surgery for treatment, but ERCP is now a viable, cost-effective, and preferable alternative.

Advanced endoscopic interventions have the added benefit of being minimally invasive, less painful, and seldom require muscle paralysis.[6] More than 500,000 ERCPs are performed annually in the United States, with a majority requiring anesthesia services.[14] ERCPs are more often performed in older patients; many of whom have a greater burden of comorbid conditions.[13] While there is currently no outcome evidence performed based on prospectively randomized trials as to whether MAC or GEA is superior for patients undergoing advanced endoscopy interventions, there is convincing clinical rationale to prioritize a "MAC-first" approach in the majority of these endoscopy patients. While anesthetic plans are always tailored to each specific individual, the experienced endoscopy team will recognize that the MAC approach may be the superior one, particularly for healthier patients with a normal or near-normal body mass index (BMI). Clear communication between the endoscopist and anesthesia professional is critical. For instance, the specific indication for the ERCP (therapeutic versus diagnostic) and case duration are vital to create a shared mental model and will likely contribute to the determination of the optimal anesthetic. For example, if the intervention plan is a straightforward removal of a biliary stent, then MAC may be most appropriate. By contrast, drainage of a complex, septated pancreatic pseudocyst with necrotic walls will almost certainly require GEA. Therefore, the time and invasiveness of the intervention are vital inputs to anesthetic choice, and the advantages and disadvantages of each anesthetic technique must be considered (Table 2).

**Table 2: Advantages and Disadvantages of Each Anesthetic Plan of Care.**

| Plan of care | Advantages | Disadvantages |
|---|---|---|
| Monitored anesthesia care | Decreased side effects from inhalation anesthetic drugs<br>Decreased risk of airway injury<br>Faster cognitive recovery<br>Enhanced efficiency metrics | Over sedation/apnea<br>Frequent hypoxemic episodes<br>Challenging emergency airway management<br>Procedural interruptions due to necessary airway maneuvers |
| General endotracheal anesthesia | Secure airway<br>Fewer hypoxemic episodes<br>Quantitative capnography<br>Minimal procedural interruptions | Hemodynamic instability<br>Intubation-related injuries<br>Potential adverse drug reactions<br>Longer PACU recovery |

Abbreviation: PACU, postanesthesia care unit.

Specific facility factors similarly contribute to the choice of the optimal anesthetic. These considerations include proximity to the main operating rooms, readiness of rescue equipment, adequate post anesthesia care unit, and the availability of additional help, if needed. Other considerations include the physical footprint of the anesthesia workspace, which is often limited due to specialized equipment (eg, endoscopy supplies, radiographic imaging equipment, ancillary display/viewing towers). Communication with both the institution and endoscopy team before the procedure is important to help mitigate any untoward complications. Moreover, the prudent practitioner must always ensure a clear plan and pathway are in place in case emergent airway rescue is needed. The factors listed above may contribute to the decision to prioritize MAC.

Complex endoscopy—particularly ERCP procedures— are routinely performed in the prone or semiprone position, which can limit ready access to the airway and/or impact venous return and cardiovascular stability.[2] However, this position usually maintains pulmonary blood flow and ventilation distribution (V/Q match) in the lungs, especially in the nonintubated (e.g., MAC) patient. Furthermore, the endoscope itself can mitigate airway collapse by acting as a stent.[15] Prone position has multiple additional positive effects on respiratory function, specifically increasing functional residual capacity (FRC) and the arterial $Po_2$.[2]

A major concern regarding MAC in the prone position is the potential need for urgent or emergent access to the airway, with the potential need for emergent endotracheal intubation. One potential, provocative strategy is for an adequately trained endoscopist to perform a gastroscope-facilitated endotracheal intubation. This requires a smaller endoscope capable of being introduced into the trachea and an endoscopist who possesses these skills, readily facilitated by an anesthesia professional. The "ultraslim" gastroscope functions similarly to a bronchoscope and has an outer diameter of 5.4 mm that can accommodate an adult endotracheal tube over the scope.[16] In a review of over 3400 patients undergoing ERCP (46% with GEA versus 54% with MAC), the overall conversion rate from MAC to GEA was low at 2.3%. The authors described their successful use of gastroscope-facilitated tracheal intubation in 16 patients due to retained food in the stomach and/or hypoxia.[17] An additional benefit of the gastroscope is that aspirated material can be immediately suctioned from the trachea and bronchi, thereby decreasing the risk of respiratory complications.[17] Extubation was successful in all patients who underwent gastroscope-facilitated intubation, and no patients had radiographic evidence of aspiration pneumonia.[17]

This novel approach to rescue the compromised or failing airway obviates the most commonly identified concern by clinicians considering the use of MAC in the prone or semiprone position. The endoscopist in the above-mentioned study was self-trained in this technique, highlighting the fact that there is currently no formal training or credentialing process for gastroscope-facilitated intubation.[17] This technique should only be considered under the direct supervision of an anesthesia professional or performed by an anesthesia professional. One important caveat to using the ultraslim gastroscope for intubation is that the endoscopist must switch from the traditional side-viewing ERCP gastroscope to the ultraslim gastroscope loaded with an endotracheal tube. This exchange of gastroscopes provides the benefit of suctioning the stomach, esophagus, and hypopharynx on withdrawal—immediately before intubation—but should be performed in an expedited fashion to minimize potential delay to intubation.

Before proceeding with MAC for ERCP, risk factors for sedation-related adverse events (SRAEs) must be considered, as highlighted in Table 3. Conditions that increase the likelihood of aspiration are considered by many to be risk factors for SRAEs. Numerous studies have shown MAC to be a safe option for ERCP, especially in patients with minimal risk factors for SRAEs. A large, decade-long, population-based study at multiple endoscopy centers in the United States found no significant difference in overall serious adverse events between ERCPs

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# Appropriate Preoxygenation Before Sedation Can Increase Margin of Safety

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**Table 3: Risk Factors for Sedation-Related Adverse Events During MAC.**

| |
|---|
| Obstructive sleep apnea |
| Body mass index >35 |
| Male sex |
| ASA physical status >III |
| Emergent procedure |
| Mallampati IV/difficult airway |
| Severe gastroesophageal reflux disease |
| Esophageal/gastric mass |

Abbreviations: ASA, American Society of Anesthesiologists; MAC, monitored anesthesia care.

performed with MAC (n = 8395) versus GEA (n = 10,715; odds ratio [OR] = 1.04, 95% confidence interval [CI], 0.76–1.43).[2,3] Albeit, the majority of these patients were relatively healthy (ASA physical status I and II), and the authors did not attempt to control for selection bias. There was no significant difference in adverse events between ASA physical status I and ASA physical status II patients (OR = 0.84 [0.49–1.46]), nor was there a difference between ASA physical status III and ASA physical status II patients (OR = 1.30 [1.00–1.69]). In fact, the data suggest that only ASA physical status IV patients were noted to have a significantly higher risk of adverse events with MAC (OR = 3.19 [2.00–5.09]).[2,3] In another prospective observational study, the decision of MAC or GEA was left to the anesthesia professional, with 393 patients receiving MAC and 45 patients receiving GEA.[4] The conversion rate of MAC to GEA was 3.7%. Notably, 25% of the patients converted to GEA were ASA physical status IV patients.[2,4] Given the inherent selection bias of this study, it comes as no surprise that the mean BMI was higher in the GEA than the MAC group, as was the percentage of ASA physical status IV patients.[4,6] Nonetheless, adverse event rates between MAC and GEA were not statistically different, and the study authors concluded that MAC is feasible and well tolerated for healthier, nonobese patients who are evaluated before the procedure by an anesthesia professional.[2,4,6]

Clinical monitoring during MAC for ERCP should follow routine standards for basic anesthesia monitoring, which involves continually evaluating a patient's oxygenation, ventilation, circulation, and temperature[18]; this includes measuring noninvasive blood pressures, pulse oximetry, electrocardiography, and capnography. Many of the airway devices (eg, nasal cannulas or simple facemask) used in MAC are capable of monitoring end-tidal $CO_2$ and detect apnea well before the onset of hypoxia.[4,19] Additional monitoring modalities are available for detecting apnea before the decrease in pulse oximetry, including impedance pneumography and—less commonly used in the operating room setting—an acoustic respiration rate monitor.

All MAC anesthetics begin with adequate preoxygenation. This is crucial in preventing hypoxemia—an obvious precursor to more serious adverse events (eg, cardiac arrhythmias, hypotension, and cardiac arrest).[20] Ideally, preoxygenating for 3 minutes or 4 vital capacity breaths can provide at least 4 minutes of "safety time" before a patient begins to desaturate without adequate ventilation.[21] Adequate preoxygenation in obese patients is of the utmost importance despite the reduction in "safety time" given the decreased FRC. It is important to keep in mind that obese patients often have concomitant pulmonary and systemic comorbidities that may be further exacerbated while in the prone position despite preoxygenation. Appropriate preoxygenation before the administration of sedation increases the margin of safety should transient apnea/hypoventilation occur with the initial bolus dose of propofol. In these instances, preoxygenation allows the anesthesia and endoscopy team more time to intervene with corrective measures (eg, jaw thrust and endoscope insertion for stimulation) before the onset of hypoxemia.

There are several ways to provide supplemental oxygen to patients undergoing ERCP with MAC, including low- to high-flow nasal cannulae, procedural oxygen masks, and specialized endoscopy masks. These airway devices all vary based on the amount of fractional inspired oxygen that can be delivered. Many of these devices are also capable of providing capnography monitoring during the procedure. Before the initiation of sedation, many centers will also have the patient place a bite block into their mouth to prevent biting the endoscope. Many bite blocks have a built-in airway feature or even a suction port that can help clear airway secretions.[15] In addition to ensuring the airway delivery device is comfortable, having the patient self-position can help decrease the risk of compression or nerve injury that might otherwise be unrecognized in a patient undergoing GEA. An added benefit to self-positioning is that fewer staff are required to assist with transferring the patient as would be needed if the patient was under general anesthesia.

There are numerous additional supplements to consider during MAC for advanced endoscopic procedures. Premedication with glycopyrrolate reduces secretions and improves the efficacy of topical anesthetics.[22] In fast turnover endoscopy centers, this would need to be administered in the preoperative area to take effect before the procedure. Patients should be counseled about the side effects of each medication accordingly. Before initiating sedation, topical pharyngeal anesthesia blunts the stimulation from scope insertion. Options for topicalization include local anesthetic sprays, which usually contain benzocaine or lidocaine as the active ingredient, or viscous lidocaine, which the patient can swish around their mouth and subsequently swallow. If using benzocaine-containing solutions, it is important to use caution due to the risk of methemoglobinemia. The ideal maintenance anesthetic allows for easy titration, rapid recovery, and minimal side effects while maintaining spontaneous ventilation. Propofol is easily titrated to maintain spontaneous ventilation while simultaneously providing moderate to deep sedation.[23] If analgesia is needed, adding a shortacting opioid, dexmedetomidine, or ketamine to the intravenous anesthetic is advisable to achieve that goal.[22] In addition, endoscopic procedures can be aborted almost immediately by simply removing the scope if urgent access to the airway is required. Scope removal may result in laryngospasm, so one must be ready to urgently treat that potential complication while preparing to secure the airway. Apart from the insertion of the gastroscope, the intensity of stimulation remains relatively constant during ERCP as opposed to the fluctuations that occur during a traditional surgical operation. Due to relatively minimal or absent stimulation, titrating the anesthetic to sustain spontaneous ventilation is usually easily achieved.[20] When used alone, propofol sedation allows a return to cognitive baseline within 30 to 45 minutes of discontinuation despite delayed return of psychomotor speed and reaction time.[24] Use of MAC avoids the use of both depolarizing and nondepolarizing neuromuscular blocking drugs; many of which have their own unique side effects. There is also less postoperative nausea and vomiting if inhalational anesthetics and opioids are avoided, leading to better patient satisfaction.

GEA is not without risk. Intubation carries the risk of lip, tongue, dental, and eye injuries and, albeit rarely, bronchial rupture or inability to secure an airway and need for a surgical intervention. Succinylcholine is most often used for its rapid onset and short duration, and in the case of endoscopy, paralysis is usually not otherwise necessary. Potential adverse effects of succinylcholine

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# MAC vs. General Anesthesia for ERCPs Debate (Cont'd)

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include muscle pain, myoglobinemia, myoglobinuria, and malignant hyperthermia.[20] The use of nondepolarizing muscle relaxants is associated with an increased risk of postoperative pulmonary complications from residual neuromuscular blockade.[24] The anticholinergic effects associated with reversal of these paralytics must also be considered, though this may be less of an issue at institutions where sugammadex is readily available. The depth of anesthesia required during GEA increases the risk of hypotension, which can subsequently lead to an increased risk of myocardial injury, renal injury, and possibly death.[26] Because ERCP is performed in the prone or semiprone position, multiple people are required to safely position and secure the patient while turning from supine to prone position on the fluoroscopy table. There is always a risk of endotracheal tube displacement or accidental extubation during positioning. Finally, the NORA locations often have less support from colleagues and other team members to help during emergencies and anesthesia turnovers, which can subsequently decrease efficiency of the facility. Perbtani et al[5] evaluated the impact of GEA on various efficiency metrics in a large interventional endoscopy center. More than 1400 patients who underwent 1635 interventional endoscopic procedures over a 6-month period were analyzed based on time stamps for anesthesia ready time, endoscopist ready time, procedure time, room exit time, time interval between successive procedures, nonprocedural time elapsed, total time elapsed in the endoscopy unit, and number of cases per room per day.[2,5] All process efficiency metrics—aside from the time interval between successive procedures—were significantly prolonged among the patients who were intubated compared with nonintubated patients in the interventional endoscopy unit. A secondary aim of the study showed that patients undergoing ERCP were intubated more frequently than those undergoing other procedures (41.3% vs 12.4%).[2,5]

In conclusion, MAC offers significant benefits over GEA in properly selected patients undergoing ERCP. These benefits include faster cognitive recovery, decreased side effects from the medications used to induce GEA, decreased risk of airway injury, decreased postoperative pulmonary complications, and reduced time spent at the hospital due to quicker induction and shorter time to discharge, thereby enhancing efficiency metrics for the unit, the providers, and the patients. With proper monitoring, supplemental oxygen, and sedation carefully titrated to maintain spontaneous ventilation, MAC during ERCP is a safe and often a superior alternative to GEA.

## CON: GEA OFFERS MAJOR ADVANTAGES OVER MAC

**Luke S. Janik, MD, and Jeffery S. Vender, MD, MCCM**

ERCP is a frequently performed procedure in the diagnosis and management of pancreaticobiliary disease. Each year, >500,000 ERCP procedures are performed in the United States, with the most common indications being bile duct stones and strictures of the biliary and pancreatic ductal systems.[27] ERCP is an invaluable tool in the management of liver, biliary, and pancreatic disease, but is generally considered the most high-risk procedure performed in the GI suite, with an overall procedural complication rate of 4%.[28] Procedural complications include pancreatitis (2%–10%), cholangitis/sepsis (0.5%–3%), postsphincterotomy bleeding (0.3%–2%), duodenal perforation (0.08%–0.6%), and death (0.06%).[28,29] However, what may be more concerning to those in the anesthesia profession is the high rate of SRAEs during the procedure, with an incidence reported as high as 21%.[6,7] This begs the questions of who should be administering anesthesia and monitoring the patient during ERCP and what type of anesthesia should be administered. In this "Pro-Con," we argue that a qualified anesthesia professional should administer the anesthesia for ERCP, and that GEA offers significant advantages over MAC.

There is wide variability in the delivery models of anesthesia for ERCP. The 3 most common models of anesthesia care delivery are (1) endoscopist-directed sedation (EDS), (2) MAC, and (3) GEA. In the first model, EDS, the intravenous sedation is administered by a member of the GI team—usually a nurse—under the supervision of the endoscopist, who is often simultaneously performing the procedure. The use of traditional "conscious sedation" with titration of benzodiazepines and narcotics has generally fallen out of favor due to high procedure failure rates, poor patient satisfaction, and poor endoscopist satisfaction.[30] Consequently, EDS has adopted the use of propofol sedation by nonanesthesia professionals, which the gastroenterology community touts as safe and effective.[31–33] In the other 2 models of anesthesia care delivery, the patient is under the care of a qualified anesthesia professional, receiving either MAC with propofol-based sedation or GEA. The choice of anesthesia care delivery model is institution specific and depends on available resources and personnel, procedural complexity, patient characteristics and comorbidities, and individual preferences.

Before we discuss how the anesthesia should be performed, we need to acknowledge where it is performed. The risk of anesthesia in remote locations is widely recognized. An analysis of the ASA Closed Claims database reviewed malpractice claims against anesthesia professionals in remote locations and demonstrated that adverse events in remote locations resulted in higher rates of severe complications—including death and permanent brain damage—than adverse events in the operating room. In fact, the proportion of death was almost double in remote locations versus the operating room (54% vs 29%).[11] Respiratory events were more common in remote locations than the operating room (44% vs 20%), with inadequate oxygenation/ventilation identified as the mechanism of injury in 21% of remote location claims versus 3% of operating room claims.[11] The closed claims data specific to the GI suite demands further attention. Compared to all other remote venues, the GI suite accounted for the highest percentage of anesthesia malpractice claims (32%), the highest proportion of claims associated with oversedation (58%), and the highest rate of MAC utilization (>80%).[11] These data do not come as a surprise to anesthesia professionals. Unfamiliar locations, lack of resources, poor ergonomics, limited assistance, variable cultures of safety, and the physical distance from additional anesthesia equipment and personnel are daily obstacles in the GI suite. In addition, the patients are often older and sicker.[11] ERCP introduces other unique challenges, including the routine use of the prone position, limited access to the airway, and the use of an endoscope capable of causing airway obstruction and laryngospasm. Taking all of these challenges into consideration, anesthesia for ERCP carries substantial risk and should be approached with caution.

Proponents of MAC for ERCP point to numerous retrospective and prospective studies—mainly from the gastroenterology literature—which conclude that the technique is safe and effective.[4,6,8,33,34] In a prospective study comparing MAC to GEA, Berzin et al[6] reported an overall rate of SRAEs of 21%. Specific adverse events in the MAC cohort included hypoxemia (12.5%; defined as oxygen saturation <85%), unplanned mask ventilation (0.6%), unplanned intubation (3%), and procedure interruption (5%).[6] From these data, the authors concluded that "minor sedation related events were common (21%) but lead to transient interruption of the procedure in only 5% of cases." They casually dismissed the 3% incidence of

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# Endoscopy Suites Have Higher Rates of Severe Adverse Events vs. Operating Room Cases

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unplanned intubation by stating that "airway access was easily obtained on the rare occasion unplanned intubation was deemed necessary." In a similar prospective study of ERCP under MAC, Zhang et al[7] found that sedation-related complications occurred in 18% of patients, with hypoxemia (defined as oxygen saturation <90% for at least 2 minutes) occurring in 9% of patients, and >33% of patients experiencing multiple hypoxemic episodes. The authors noted that the incidence of hypoxemia in their study was comparable to the hypoxemia rate in other similar studies and, thus, concluded that "sedation by anesthesia personnel for ERCP is safe." In a retrospective review of MAC for ERCP, Yang et al[9] reported an incidence of hypoxemia (defined as oxygen saturation <90%) requiring airway manipulation in 28% of cases, with 1.6% of patients requiring conversion to GEA due to food in the stomach. Despite their findings, the authors concluded that "propofol can be used safely and effectively as a sedative agent for patients undergoing ERCP."

How can studies that report such high rates of SRAEs, hypoxemic episodes, and necessary airway maneuvers conclude that the sedation is "safe" or "feasible" or "appropriate?"[4,6–9] Just because a critical event does not lead to a critical outcome, does not mean the event is any less critical! The interpretation of data ultimately relies on the lens through which they are viewed. A gastroenterologist may not be alarmed by an unplanned intubation rate of up to 3%,[6] or hypoxemia rates as high as 33%,[7] as long as the patient did not suffer any long-term sequelae. However, an anesthesia professional who is responsible for emergency airway management and cardiopulmonary resuscitation may view each of these hypoxemic episodes as a "near-miss" event. Keep in mind, pulse oximetry is a measure of oxygenation, not ventilation, and it cannot reliably be used to detect hypoventilation and progressive hypercarbia.[35,36] Hypoxemia in the setting of supplemental oxygen use—as is standard during MAC for ERCP—is a late marker of hypoventilation and is a harbinger of impending respiratory arrest.

For the sake of argument, let's consider a different scenario. If we drive without wearing seatbelts for a year and are never harmed in any accidents that occur, are we correct to conclude that driving without seatbelts is safe, feasible, and appropriate? Normalizing and accepting high rates of hypoxemia during MAC for ERCP, while in a remote location, in the prone position, and with limited airway access, sets a dangerous precedent. We admit that it is difficult to define an "acceptable" rate of SRAEs and hypoxemic episodes during sedation. However, in our opinion, the rates of SRAEs and hypoxemic episodes reported in the aforementioned studies are worrisome and should be presented as a patient safety concern, rather than being dismissed as an inconsequential event.

Now, let's turn our attention toward the evidence in support of GEA for ERCP. In a randomized controlled trial comparing the safety of MAC to GEA for ERCP, the results clearly favor GEA.[10] This study included patients identified to be high risk for SRAEs including those with a STOP-BANG (Scoring system involving: Snoring, Tiredness, Observed apnea, Blood Pressure, Body mass index, Age, Neck circumference, Gender) score ≥3, abdominal ascites, BMI ≥35, chronic lung disease, ASA physical status score >3, Mallampati class 4 airway, and moderate to heavy alcohol use. The rates of SRAEs were markedly higher in the MAC group compared to the GEA group (51.5% vs 9.9%).[10] In the MAC group, hypoxemia (defined as oxygen saturation <90%) occurred in 19% of patients, with 45% requiring one or more airway maneuvers and 8% requiring bag-mask ventilation.[10] Conversely, there were zero incidents of hypoxemia or airway maneuvers in the GEA group. The ERCP procedure had to be interrupted in 10.1% of the MAC group, requiring conversion to GEA for respiratory instability (8%) and retained gastric contents (2%).[10] Of note, hypotension requiring a vasopressor occurred at similar rates in both groups, and there were no differences in procedure time, technical success, and patient recovery time.[10]

Putting the data aside for a moment, let's step back and discuss the reality of crisis management from an anesthesia professional's perspective. Airway compromise in the prone position, while isolated in a remote location, and with limited help and resources is every anesthesia professional's nightmare—as it should be. When every second matters, it may feel like an eternity to withdraw the endoscope, move the fluoroscopy equipment out of the way, bring the stretcher into the room, and turn the patient supine. By the time the patient is appropriately positioned to manage the airway, they may be on the verge of respiratory arrest. Yes, this is a relatively rare event during sedation for ERCP, but it is preventable. Why take this risk when the airway could be secured initially with endotracheal intubation in an elective, controlled manner? With the high rates of hypoxemia associated with sedation during ERCP and the numerous challenges associated with unplanned intubation in this environment, GEA is simply the logical choice.

There is a perception among gastroenterologists that MAC is quicker than GEA, requires less turnover time, and enables higher patient throughput. Although some data exist to support this perception,[5] other data suggest that any time saved during sedation is likely offset by frequent procedural interruptions due to airway compromise.[10] In reality, GI suite efficiency is a complex product of many different variables (including procedural efficiency by the endoscopist), and it is shortsighted to think that efficiency is solely related to the presence or absence of an endotracheal tube. There is also a perception that MAC is inherently gentler, safer, and less invasive than GEA. Yes, the use of GEA introduces its own risks, including the potential for dental injury, residual neuromuscular blockade, hemodynamic instability, and adverse drug reactions. However, when comparing all of these risks with the risk of airway compromise during MAC for ERCP in the prone position, there frankly is no comparison. Our job as anesthesia professionals is to mitigate risk, and the potential for airway compromise during MAC for ERCP is a risk not worth taking.

Until further large scale, multi-center randomized controlled trials are conducted, the controversy regarding MAC versus GEA for ERCP will persist, and the standard of care will remain undefined. What all anesthesia professionals can agree on, however, is that regardless of the anesthetic technique, the anesthesia should be administered by a qualified anesthesia professional. In the United States, EDS for ERCP decreased from >50% of cases in 2005 to 5% in 2014, but it remains prevalent in Europe and other countries.[3] A retrospective review of nearly 27,000 ERCPs performed over a 10-year span showed that EDS resulted in a higher rate of adverse events (OR = 1.86) and was nearly twice as likely to require an unplanned intervention than anesthesia-provided sedation.[3] Studies also demonstrated that EDS led to a higher rate of sedation failure, and consequently procedural failure, than anesthesia-administered MAC or GEA.[30,34] To make matters worse, EDS resulted in both poor patient satisfaction and poor endoscopist satisfaction.[33] In our opinion, the EDS model for ERCP is a threat to patient safety and should be abandoned. We strongly believe that propofol sedation should only be administered by a qualified anesthesia professional equipped with the ability to quickly recognize airway compromise and the skills to manage an airway in the event of emergency. These skills fall outside the scope of practice of gastroenterology physicians, nurses, and technicians.

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# A Qualified Anesthesia Professional Should Determine the Optimal Anesthetic for Specified Patients and the Clinical Circumstance

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MAC anesthesia during ERCP is associated with high rates of hypoxemia, airway maneuvers, and SRAEs. These risks coupled with the inherent dangers of anesthesia in remote locations raise significant concern about the safety of MAC for ERCP in the prone position. To quote the wise anesthesiologist Dr. Carl Hug Jr, perhaps MAC should stand for "Maximal Anesthesia Caution" rather than "Monitored Anesthesia Care."[37] We believe that all patients undergoing ERCP procedures should be under the care of a qualified anesthesia professional and that GEA offers significant advantages over MAC.

## SUMMARY

This Pro-Con article was prompted by the growth in complex endoscopy procedures over recent years coupled with the lack of large randomized controlled trials to support a definitive anesthetic technique for patients having ERCP. The debate is particularly important because of the incidence of comorbidities and because the procedure involves a shared airway. The benefits of MAC include fewer hemodynamic perturbations, decreased side effects from inhalation agents, faster cognitive recover, and shorter overall procedural time, which must be weighed against the incidence of critical events due to impaired oxygenation and/or ventilation known to occur during MAC. The 2 approaches highlighted in this discussion emphasize the importance of having a qualified anesthesia professional determine the optimal anesthetic for a particular patient and clinical circumstance.

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# Evolving Standards for Anesthesia During Advanced GI Endoscopic Procedures

*by Richard C. Prielipp, MD, MBA, FCCM, and Stuart K. Amateau, MD, PhD, FASGE, FACG, AGAF*

Patients undergo over 11 million colonoscopies, >6 million upper gastrointestinal (GI) endoscopy procedures, 180,000 upper endoscopic ultrasound examinations, and close to 500,000 endoscopic retrograde cholangiopancreatography (ERCP) interventions each year in the United States.[1] Total expenditures for GI diseases exceed $136 billion per annum and continue to increase annually.[1] Anesthesia care is increasingly required during these procedures as patients present with a host of significant medical comorbidities, advanced frailty, and decreased physiological reserves. Moreover, patients now often undergo increasingly complex and extensive interventional procedures as they simultaneously present with more advanced disease. Thus, it is not surprising that the authors of the current Pro/Con debate article in this issue of the *Anesthesia & Analgesia* present 2 opposing perspectives regarding current anesthetic recommendations for GI endoscopy procedures.[2] While these authors practice in similarly impressive, high-performing high-volume procedural centers, they posit different anesthesia care recommendations for selected patients undergoing GI endoscopy procedures. Clinicians will surely ponder their own choice of the "best anesthetic" in these situations for these challenging patients.

Why the ambiguity? The practice of medicine often varies when medical science lacks validated outcome data, and a standard of care remains undefined. This variability is usually the consequence of patient comorbidities, inconsistencies of practitioner skills and experience, evolving procedural needs, inconsistent resources, and even variation of the physical facilities (operating room, procedural area, GI suite, inpatient versus outpatient setting, etc). Moreover, to conduct an optimal, safe, and efficient anesthetic, anesthesia professionals must also understand the unique challenges and requirements of the GI proceduralist. Indeed, historically, endoscopists often utilized moderate sedation (the so-called endoscopist-directed sedation [EDS] model) for virtually all cases, including patients with significant comorbidities and even those undergoing complex interventions such as ERCP. This EDS model was chosen, in part due to limited access to advanced anesthesia services and providers and the key requirement for rapid turnover between cases. Thus, this bedside "conscious sedation" approach remained the norm throughout much of the 1990s. But, the landscape has changed significantly in the last 2 decades, with the widespread utilization of intravenous propofol and the increased availability of anesthesia professionals to facilitate efficient, safe, deep sedation, or even general anesthesia as needed, on a routine basis. Endoscopists recognize the utility and benefits of deep sedation provided by anesthesia professionals, as this approach decreases failed interventions, improves the patient experience and satisfaction, and optimizes postprocedure recovery from sedation—all while ensuring patient safety.[3] Thus, the EDS model has markedly diminished, and there are fewer advocates for this approach within the gastroenterology community in the current era. Moreover, as procedures of even greater complexity and duration are performed, such as advanced ERCP and third-space endoscopy, general anesthesia is often required to ensure a secure airway and a stable, motionless surgical field for ease and safety of distal cannulation.[4]

Determining the level of sedation appropriate for a particular endoscopic intervention involves a complex assessment of patient and procedure characteristics against the backdrop of available resources and operational requirements. On the one hand, a growing number of GI endoscopists now offer minimal or even no sedation options for basic colonoscopy in healthy, fit, and motivated patients. Expert techniques, such as water exchange, minimize discomfort, and this approach can even avoid typical postsedation restrictions.[5] The current nature of endoscopy centers, with the first patient-physician encounter occurring mere minutes before a scheduled procedure, further intensifies the selection of appropriate sedation goals. An advanced scheduling team typically includes knowledgeable health care providers to aid in these initial triage decisions; however, other units have moved toward deep sedation as the standard—a one-size-fits-all patients approach. General anesthesia is then reserved for a handful of patients falling outside the criteria deemed optimal for a busy ambulatory care center.

For patients receiving deep sedation via monitored anesthesia care (MAC) or general anesthesia, good practice involves early preprocedure communication between the endoscopist and anesthesia professional regarding the appropriateness of the selected anesthetic as well as the position of the patient. Position is 1 key variable, as patients positioned in either the prone position as with ERCP or the lateral position as with most upper and lower endoscopy procedures have the added safety of airway anatomy and gravity promoting flow of regurgitated contents out of the mouth rather than into the trachea. Thus, patients requiring supine positioning may require conversion to general anesthesia and endotracheal intubation to avoid passive aspiration of foregut contents. Other patients deemed to be at high risk of aspiration or loss of the airway should prompt either a step up to general anesthesia or consideration of a step down to a less intense level of sedation. In addition, patients with prior esophageal surgery (eg, Ivor-Lewis esophagectomy) will require special precautions, a secure airway, and general anesthesia for virtually all GI interventions. While general anesthesia allows for the broadest range of interventional options, this should not be the default position, as it accrues greater expense, time, resources, and likelihood of greater hemodynamic instability and potential oral trauma compared to deep sedation.

See "GI Procedures," Next Page

# Communication Between GI Proceduralist and Anesthesia Professional is Paramount Prior to Procedure

From "GI Procedures," Preceding Page

Today, at least in the western hemisphere, high-functioning endoscopy units use deep sedation (MAC) for the vast majority of patients, with general anesthesia reserved for select patients that require scheduling within a hospital setting. The added expense and the use of resources required for general anesthesia are justified by the improved safety, experience, efficiency, and outcomes. Thus, we believe that deep sedation (MAC) or general anesthesia will soon become a virtual standard of care for patients having complex upper endoscopy procedures with procedural interventions. We hope readers enjoy this debate article within the Journal as it further explores 2 very different perspectives on the optimal anesthetic for upper GI endoscopy and ERCP procedures. In addition to all the factors cited above, the potential for adverse patient events, with the potential of medicolegal liability, undoubtedly contributes to this decision-making process.[6] Indeed, litigation has increased commensurate with the increased intensity of GI interventions and the demands of efficient throughput of an often elderly, frail patient population. Injuries range from minor dental injuries and aspiration pneumonia to cardiac arrhythmias and adverse respiratory events resulting in brain damage or even death.[6,7] Tort claims usually involve allegations of inappropriate patient selection, inadequate patient assessment or preparation, and oversedation in those without a secured airway.[6,7] Indeed, most experienced clinicians are aware of at least 1 endoscopy case performed under moderate/deep sedation or general anesthetic that "went badly" and resulted in significant patient injury or death. We suspect that the erudite discussion from our expert authors will assist clinicians in optimizing their future anesthetic choices during endoscopy procedures. As with so many other clinical situations, there is rarely, if ever, an absolute approach that can be recommended, mandated, or applied to all patients in all settings.

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# A Best Practice for Anesthesia Work Area Infection Control Measures: What Are You Waiting For?

*by Jonathan E. Charnin, MD, FASA; Melanie Hollidge, MD, PhD; Raquel Bartz, MD, MMCi; Desiree Chappell, CRNA; Jonathan M. Tan, MD, MPH, MBI, FASA; Morgan Hellman, RN, BSN; Sara McMannus, RN, BSN, MBA; Richard A. Beers MD; Michelle Beam, DO, MBA, FASA; and Randy Loftus, MD*

## INTRODUCTION

Infection prevention is of paramount importance for anesthesia professionals in 2022 given emerging infectious diseases such as COVID-19,[1] Monkeypox,[2] *Candida auris,*[3] and the persistent nature of surgical site infections (SSIs) associated with increased patient morbidity and mortality.[4-6] Further, as any infection can lead to sepsis, infection prevention is sepsis prevention.[7] Evidence-based basic perioperative infection control measures for the anesthesia work area are of proven efficacy for viral[8] and bacterial pathogens, generating substantial reductions in pathogen transmission and subsequent infection.[8-10] It is time for anesthesia professionals, who have always been leaders in patient safety, to leverage the solid platform of published evidence to improve the safety of our patients through infection prevention.[11]

In this review we highlight important implementation features for basic preventive measures with few perceived barriers for implementation. These approaches are based on both current literature and pertinent infection control guidelines (Society for Healthcare Epidemiology of America [SHEA],[12] Association for Professionals in Infection Control [APIC],[13] Centers for Disease Control and Infection Prevention [CDC],[14] American Society of Anesthesiologists [ASA],[15] and the American Association of Nurse Anesthesiology [AANA][16]). We describe four pillars of perioperative infection control measures applicable to all perioperative providers including patient decolonization, hand hygiene, vascular care, and environmental cleaning optimized by monitoring and feedback.[8,12]

The recommended interventions represent best practices designed to address the primary routes of infection that include 1) direct contamination of the wound, 2) contiguous spread following patient skin contamination occurring as a result of existing colonization or colonization resulting from patient care, 3) aerosolization of particles contaminated by pathogens arising from various anesthesia work area reservoirs such as contaminated environmental surfaces/equipment, and 4) hematogenous spread occurring as a result of injection of bacterial pathogens via injection port, syringe tip, and/or medication vial contamination.[17] Importantly, these recommendations are cost-effective,[18] practical,[9] and with confirmed implementation feasibility.[10]

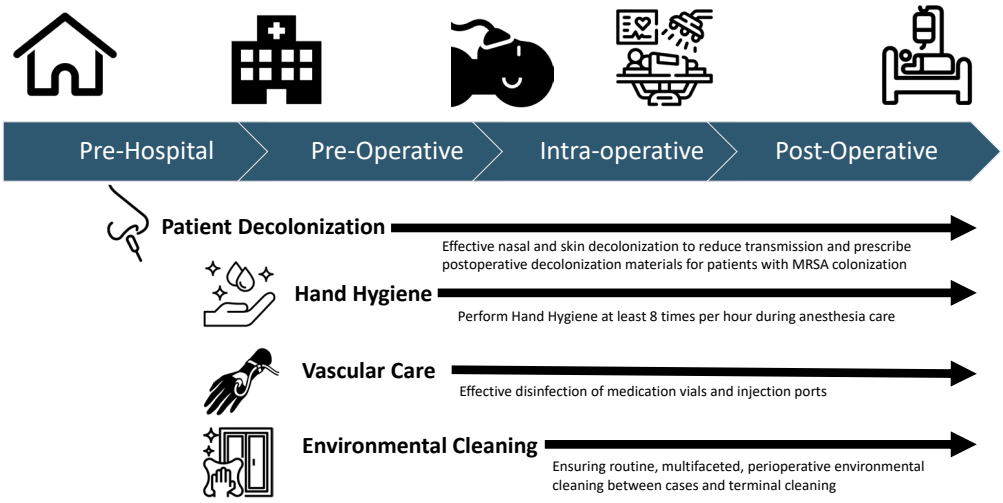


*Figure 1: Evidence-based high-value opportunities to mitigate transmission of infection across the perioperative continuum.*

While each of these preventive measures may sound familiar, and it may initially seem that you and your colleagues are already employing these practices, please carefully consider the implementation features of each recommendation. Using the right "dose" of the intervention is important to obtain the benefits for your patients.[8-10,19] Figure 1 is an infographic that was developed to depict how infection prevention extends across the perioperative continuum. A multifaceted approach involving patient decolonization, hand hygiene, vascular care, and environmental cleaning improvement efforts implemented in parallel during the process of patient care and optimized by feedback is supported by rigorous study of the perioperative epidemiology of bacterial transmission,[20-24] and of proven efficacy.[8-10] However, single interventions, such as hand hygiene,[25,26] patient decolonization,[27] or environmental cleaning[28] without feedback optimization are prone to failure.

## PATIENT DECOLONIZATION:

**Recommendations:**

1. Two doses of 5% nasal povidone iodine within one hour of the surgical incision[8,29] and use of 2% chlorhexidine gluconate wipes on the morning of surgery.[8,10,30]

   OR

2. At least 2 days of treatment (ideally the day before and the day of surgery) with 5% nasal mupirocin ointment with 2% chlorhexidine gluconate wipes or 4% shampoo.[30-32]

3. Prescribe post-discharge decolonization for your patients colonized with *methicillin-resistant Staphylococcus aureus* (MRSA) as a result of the health care exposure.[32]

**Rationale:** The epidemiology of perioperative *S. aureus* transmission involves pathogen colonization of patient skin sites (nares, axilla, and/or groin). [8,10,33-35] Postoperative infection development is strongly tied to *S. aureus* colonization at these sites.[20,34,35] As stated in recommendations 1 and 2 above, decolonization of patient skin sites reduces surgical site infections.[8,10,30-32] The optimal timing of decolonization interventions still requires more research. Postoperative decolonization of patients colonized with MRSA occurring as a result of the health care exposure can significantly decrease the risk of invasive infection development up to one year following the health care exposure.[32] Prevention of perioperative transmission resulting in colonization can augment the latter.[8,10]

**Key Implementation Features:** Choice of decolonization agent is important with increasing antibiotic resistance associated with an increase in worldwide mortality.[36,37] Both iodine and mupirocin are efficacious for SSI prevention.[29-31] Nasal mupirocin has been associated to some degree with increasing resistance,[38] whereas iodine has not.[39,40] Iodine can be managed preoperatively by the anesthesia professional with two doses given prior to incision.[8,29] whereas nasal mupirocin requires 2–5 days of treatment.[30,31]

**See "Workplace Infection," Next Page**

# Four Pillars of Infection Control Are Important to Reduce Unwanted Perioperative Infections

From "Workplace Infection," Preceding Page

Specific monitoring of patient and provider compliance with prescribed decolonization components is important. Targeted feedback to providers and monitoring of expected utilization of decolonization supplies are also important.[8,10]

## HAND HYGIENE

**Recommendations:**

1. Increase hand hygiene frequency during anesthesia care. Perform hand hygiene at least 8 times per hour[41] during anesthesia care and at least 4 times per hour while providing care in critical care environments.[42]
2. Improve the frequency and quality of environmental cleaning to aid hand hygiene improvement efforts.[8-10,43,44]

**Rationale:** Contact with the operating room environment is frequent and fast-paced during the provision of anesthesia care, often involving simultaneous touching of the patient and the environment/equipment.[45] Given the demonstrated link between hand and environmental reservoirs,[41] improved hand hygiene can reduce potential environmental infectious transmission events.[41,43,46] Ideally, hand hygiene is performed before and after patient contact, after bodily fluid exposure, after contact with the contaminated environment, and before performing a clean/aseptic task:[41,47] These are the "5 Moments of Hand Hygiene" described by the World Health Organization (WHO). During anesthesia care, hand hygiene must be performed frequently and thoughtfully to capture as many opportunities to reduce the transmission of pathogens as possible. While it may not be possible to perform hand hygiene after every event identified by the WHO guidelines, anesthesia professionals must do more to reduce the transmission of pathogens in the operating room. Inferred from published data, performing hand hygiene at least eight times hourly would significantly reduce potential transmission events.[41] In a related step, more frequent and better-quality environmental cleaning can reduce the potential for transmission events associated with hand contamination.[8,10,41,43,46] Double gloving during induction may augment WHO-based hand hygiene efforts, but further clinical study is indicated before adoption given only simulated environmental testing of this approach.[45]

**Key Implementation features:** It is important to have hand sanitizers stationed in easy reach of intraoperative providers, including ideally in several places around the anesthesia work area, to facilitate use during fast-paced patient care.[41,43,44] Consider placing alcohol-based

hand sanitizers on the anesthesia machine, mounted to the intravenous pole[8,10] and on the provider waist.[41] The importance of hand hygiene is not limited to anesthesia team members. All members of the perioperative team (i.e., circulating nurses, scrub technologists, surgeons, clinical anesthesia technologists, trainees, and equipment representatives) should employ the recommended measures when providing perioperative patient care.

## VASCULAR CARE

**Recommendations:**

1. Disinfect injection ports, using 70–90% isopropyl alcohol prior to access. We suggest hard scrubbing to create friction for 5–30 seconds followed by drying.[48-53] If using caps designed to clean needleless connectors, use products proven to be effective and follow manufacturer recommendations. Some of these devices require at least 10 seconds of contact time to be effective.[49]
2. Avoid use of open lumens (e.g., uncovered stopcocks) as they are at increased risk of contamination, cannot be disinfected well once contaminated,[50] and contamination has been repeatedly associated with increased patient mortality.[20,52]
3. Clean all medication vials with an alcohol wipe after the dust cover is removed from the vial and prior to access to prevent contamination and infection.[53] Keep injection ports, syringe tips, and IV tubing off the floor.[49]

**Rationale:** Injection ports and medication vials should be disinfected by scrubbing with a 70–90% isopropyl alcohol swab prior to each connection.[8,10] While there is no consensus for duration of injection port scrubbing with ethanol swabs, we recommend a total time of 5–30 seconds with hard rubbing to create friction followed by air drying.[48-53] Scrubbing in this manner followed by 30 seconds of drying time was shown to eliminate injection of bacteria from anesthesia professional hands in a randomized *ex vivo* study.[48]

Research has shown that up to 50,000 colony forming units of live bacteria are injected into the intravenous (IV) fluid pathway as a result of breaches in good vascular access aseptic practice as described above.[48] This is a primary route of surgical site and blood stream infection development[54] which can increase patient mortality severalfold.[55] Importantly, intraoperative stopcock contamination has been repeatedly associated with increased patient mortality and directly linked by advanced molecular typing to postoperative infection development.[20,56] Randomized controlled clinical trials at several centers[41] have shown that improved vascular care through use of injection ports with disinfecting caps mounted to the IV pole can generate substantial reductions in pathogen transmission and infectious complications. With recent confirmation of intraoperative contamination of a patient intravenous stopcock with SARS-CoV-2,[9] the importance of these recommendations extends beyond bacterial pathogens.

**Key Implementation Features:** Have alcohol pads and alcohol disinfecting caps close to providers, allowing easy access to disinfection tools.[44] Use an appropriate disinfection time for each method of disinfection.[48-50]

See "Work Place Infection," Next Page

# Anesthesia Professionals Can Collaborate with Perioperative Professionals to Reduce Infection Risk

From "Work Place Infection," Preceding Page

## ENVIRONMENTAL CLEANING

**Recommendations:**

1. Implement postinduction/sedation cleaning using a 2-hit approach involving wipes containing at least one alcohol and a quaternary ammonium compound.[43,46] Use microfiber cloth to increase removal of the bioburden.[28]
2. Organize the environment into clean/dirty spaces.[46]
3. Augment surface disinfection cleaning with ultraviolet irradiation with proven efficacy, effectiveness, and implementation feasibility.[9] Use monitoring for targeted implementation of more advanced cleaning procedures.[10,21,57]

**Rationale:** Perioperative environmental cleaning is multifaceted, involving routine, between-case cleaning, and terminal cleaning. Environmental contamination peaks during induction and emergence of anesthesia, periods of patient care that correlate with nadirs in hand hygiene compliance.[43] The anesthesia work area environment, represented by the adjustable pressure-limiting valve and agent dial of the anesthesia machine, is a potent transmission vehicle with transmission events directly linked to infection development.[20,53] At least 50% of *S aureus* SSIs can be linked to ≥1 anesthesia work area reservoir at the time of the surgery.[21] In a study performed at Dartmouth Hitchcock Medical Center, postinduction cleaning, organization of clean/dirty spaces, use of microfiber cloths, and use of multimodal surface disinfection wipes was associated with a significant reduction in the number of measured reservoirs exceeding 100 CFU per surface area sampled,[46] a threshold of contamination associated with high-risk transmission events subsequently linked to infection.[8,10,20,56] These results were similar to a well-designed crossover trial in the ICU environment where increased frequency of cleaning and use of microfiber cloths reduced bacterial contamination.[28] When ultraviolet C light (UV-C) is employed as part of an evidence-based, multifaceted approach (including improved frequency and quality of surface disinfection environmental cleaning and augmentation with UV-C, patient decolonization, vascular care, and hand hygiene), substantial reductions in *S. aureus* transmission, SARS-CoV-2 transmission, and SSIs can be achieved.[9]

**Key Implementation Features:** Employ postinduction/sedation cleaning to address an important peak in environmental contamination, organize clean/dirty spaces,[43,46] and augment surface disinfection cleaning with use of evidence-based UV-C.[8-10,58] It is important that UV-C devices selected take into account the importance of operating room time,[59] that implementation strategies have been delineated, and that they are of proven efficacy for prevention of intraoperative transmission of bacterial and viral pathogens.

## CONCLUSION

Anesthesia teams are well positioned to work collaboratively with the perioperative surgical/nursing team to maximally attenuate perioperative bacterial transmission and subsequent infection. The basic infection control measures have been developed and rigorously tested with proven efficacy, effectiveness, and implementation feasibility and practicality. It is up to anesthesia professionals to act on this information to improve perioperative patient safety.

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*Conflicts of Interest: Randy Loftus, MD, reports current research funding from NIH R01 AI155752-01A1, "BASIC trial: Improving implementation of evidence-based approaches and surveillance to prevent bacterial transmission and infection" and has received funding from the Anesthesia Patient Safety Foundation, Sage Medical Inc., BBraun, Draeger, Surfacide, and Kenall, has one or more patents pending, is a partner of RDB Bioinformatics, LLC, and 1055 N 115th St #301, Omaha, NE 68154, a company that owns OR PathTrac, and has spoken at educational meetings sponsored by Kenall and BBraun. The University of Iowa uses RDB Bioinformatics PathTrac system for measuring bacterial transmission.*

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*Desiree Chappell, CRNA, is on the Speakers Bureau for Medtronic and Edwards LifeSciences, and the Advisory Board for ProVation.*

*Jonathan Charnin, Melanie Hollidge, Raquel Bartz, Morgan Hellman, Sarah McMannus, Richard Beers, and Michelle Beam report no conflicts of interest.*

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# Perioperative Infection Control is an Important Patient Safety Concern

From "Work Place Infection," Preceding Page

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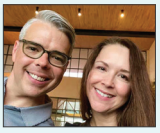
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