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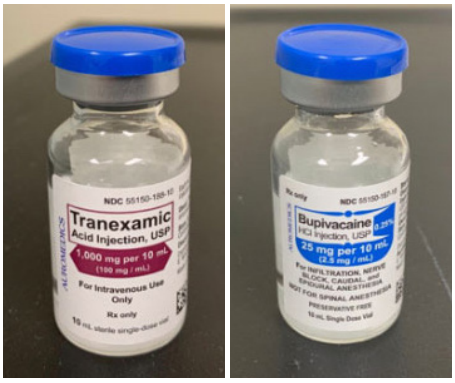
Unraveling a Recurrent Wrong Drug-Wrong Route Error—Tranexamic Acid in Place of Bupivacaine: A Multistakeholder Approach to Addressing this Important Patient Safety Issue

by Paul A. Lefebvre, JD; Patricia Meyer, PharmD, MS; Angela Lindsey; Rita Jew, PharmD, MBA; and Elizabeth Rebello, RPh, MD

INTRODUCTION

Notwithstanding technological advances and the ongoing efforts of patient safety advocates, medication administration errors routinely occur in health care facilities across the country.[1-2] Each day, anesthesia professionals overcome challenges that commonly contribute to medication errors, such as a lack of standardization, drug shortages, production pressures, high-stress work environments, and limited resources. The World Health Organization estimates the global cost of medication errors to be $42 billion.[3] A momentary lapse in concentration or, more frequently, systemic issues in workflow, contribute to medication errors. In addition, a medication error involving the wrong drug and the wrong route can have dire consequences for the patient.

To illustrate, we have identified a concerning trend in which anesthesia professionals have inadvertently administered tranexamic acid (TXA) intrathecally when performing neuraxial blocks. The mortality rate associated with this medication error is approximately 50%.[4] In the last 10 years, Preferred Physicians Medical (PPM), an anesthesia-specific professional liability carrier, received six reported incidents involving TXA-bupivacaine mix-ups (most occurring in the last four years). All six occurred during orthopedic procedures; however, a retrospective study suggests this TXA-bupivacaine wrong drug-wrong route medication error has also occurred during caesarean deliveries and other abdominal procedures.[4] The use of TXA has increased in recent years based on the results of several studies, including the POISE-3 trial which demonstrated decreased bleeding by up to 25% with TXA use.[5-7] As TXA is administered more frequently, it is imperative that measures are taken to prevent medication administration errors.



Submitted to the APSF Lookalike Vial Gallery by Andrea Regan, MscS, MSA, CAA.

In this article, we examine a case involving a TXA-bupivacaine mix-up, share perspectives from a multidisciplinary group of contributors, and offer recommendations to avoid recurrence of these catastrophic medication errors.

CASE STUDY

A 67-year-old male presented for left total knee arthroplasty. The patient's medical history was significant for morbid obesity, hypertension, and coronary artery disease. The anesthestic plan was a subarachnoid block with monitored anesthesia care. An anesthesia professional was also expected to administer TXA intraoperatively at the request of the surgeon. The hospital's policies and procedures stated TXA must be ordered from the pharmacy in prefilled infusion bags. However, this practice was seldom followed by the surgical team in the patient's Operating Room (OR). Accustomed to the OR's practice, the anesthesia professional removed 10 mL vials of TXA and bupivacaine from the automated dispensing cabinet in preparation for the case.

Once the patient arrived in the OR, the anesthesia professional drew up what he believed to be bupivacaine into a syringe labeled "Marcaine/Fentanyl." The anesthesia professional had difficulty administering the block due to the patient's body habitus, and he called the supervising anesthesiologist to assist. The anesthesiologist administered a 2.5 mL dose, but the block did not induce the intended effect. Within minutes, the patient reported pruritus in his perineum. The anesthesia team assumed the patient's discomfort was the result of a failed block, and they elected to convert the case to a general anesthetic. After induction, the patient was noted to have minor leg twitching. Once the procedure progressed to the point TXA was needed, the anesthesia professional discovered the TXA vial was opened, while the bupivacaine vial remained sealed and unused on the anesthesia cart. Upon recognizing the patient had received a 250 mg dose of TXA intrathecally, the anesthesia professional alerted the anesthesiologist and surgeon, and they decided to complete the procedure and evaluate the patient in the PACU.

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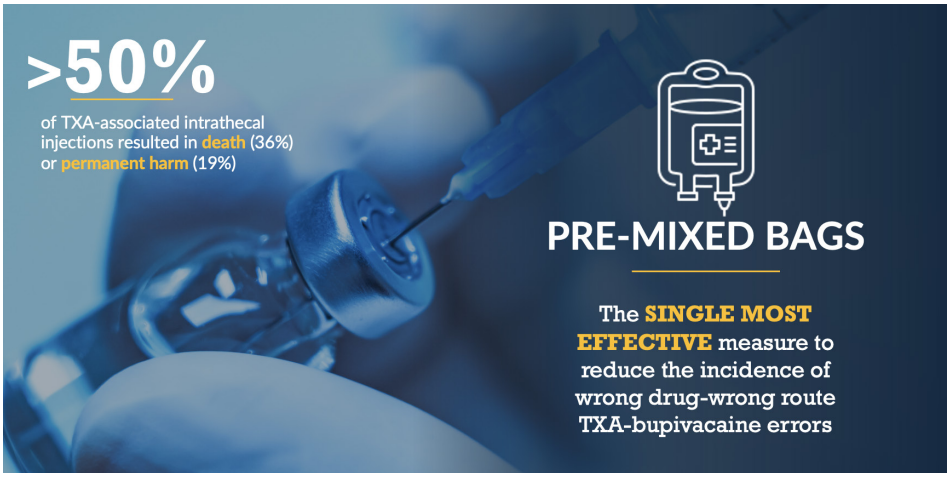

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Unacceptably High Accidental Injections of TXA into the Intrathecal Space Continue to Occur

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The patient remained intubated and on a propofol infusion upon transfer to the PACU, where he began experiencing seizures a short time later. The patient was transferred to the Neurological Intensive Care Unit (Neuro-ICU) for evaluation. There, the decision was made to take the patient back to the OR to undergo a cerebral spinal lavage. After the procedure, the neurology critical care physician elected to leave the patient on isoflurane until the seizures stopped or the inhalation agent was no longer tolerated. Isoflurane was subsequently discontinued in favor of propofol and ketamine, and the seizures were suppressed by postoperative day (POD) #3.

The patient had a lengthy and eventful stay in the neuro-ICU. He experienced delirium due to toxic and metabolic encephalopathy, and myoclonic status epilepticus requiring prolonged intubation. He was extubated on POD #14, and the nasogastric tube was removed on POD #17. The patient exhibited cognitive deficits, including both short- and long-term memory impairment. He was discharged to a rehabilitation hospital on POD #23. During his 2-week admission, the patient's cognition, memory, and motor function gradually improved. The patient was also treated for shoulder pain, which was attributed to a rotator cuff tear resulting from seizures. The patient required skilled nursing care for several weeks post-discharge. Fortunately, the patient went on to make a remarkable recovery, and his neurologist noted his executive and motor functions returned to baseline approximately 13 months after the event.

The patient and wife subsequently filed a lawsuit against the anesthesia professionals involved, the anesthesia group, the hospital, and the orthopedic surgeon. The anesthesia professional acknowledged liability at the outset of the case, and the parties conducted discovery to fully evaluate the plaintiffs' damages. The parties mediated the case a year later, and the plaintiffs settled with the anesthesia professional and the anesthesia group within the policy limits.

DISCUSSION

In a 2023 narrative review of 22 recent reports of TXA-associated intrathecal toxicity occurring from July 2018 to September 2022, it was found that 36% of the patients died and 19% had permanent harm. The permanent harm ranged from residual muscle weakness, chronic pain, T10 and L1 spine fractures associated with convulsions, mild cognitive impairment, and multiple neurological deficits to extreme chronic pain causing the patient to be bed-bound.[5] A dose-response relationship has not been determined. Patient responses have been variable, such as some patients have died after receiving 160–200 mg, whereas other patients have survived after doses of 300–350 mg. It was also noted that the lack of recognition by the perioperative team of the characteristics of the TXA toxicity caused a delay in diagnosis. The severity of patient injury in a wrong drug intrathecal administration is typically related to the toxicity of the drug that is inadvertently administered.[8] When TXA is given intrathecally, it is a potent neurotoxin that can cause neurological injury, seizures, paraplegia, ventricular fibrillation, and death.[9-12] The Human Factors Analysis Classification System was used to assess and classify human and systemic factors that contributed to the errors. Mistaking look-alike TXA ampules or vials for local anesthetics was the predominant cause of the 22 events. The authors suggested that double checking the medication with another human or technology such as a barcode scanner could have possibly prevented the errors.

The same error occurring multiple times with the accidental administration of TXA into the intrathecal space warrants a call for implementation of reliable prevention strategies in every perioperative area.[8,10-12] In 2010, the Anesthesia Patient Safety Foundation (APSF) Stoelting Conference on Medication Safety developed recommendations for new strategies for "predictable prompt improvement" of medication use in the OR.[12] The implementation of many of the recommendations has not been as widely adopted as safety experts would have liked. One of the recommendations was routine provider-prepared medications should be discontinued whenever possible and that high-alert medications should be prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients.

The ISMP developed the hierarchy of effectiveness of risk-reduction strategies, which ranked various strategies for preventing errors from least to most effective (Figure 1).[13] Risk-reduction strategies such as education, training, and policies are considered low-leverage strategies and are least effective. Although these practices do have some benefits, they rely on

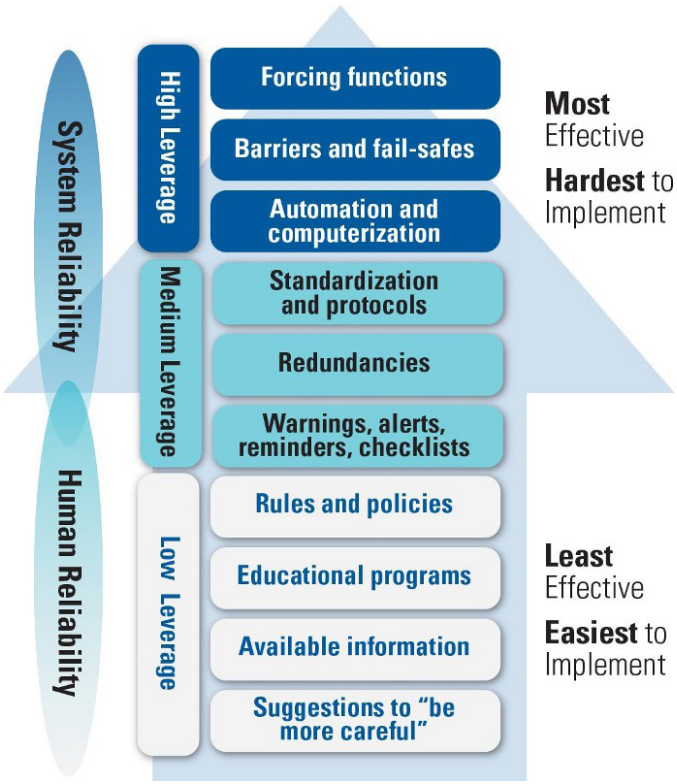

Figure 1. ISMP's hierarchy of effectiveness of risk-reduction strategies. High-leverage strategies are most effective because they can eliminate the risk of errors and associated harm by "designing out" hazards; however, they often require complex implementation plans. Medium-leverage strategies, which are easier to implement, reduce the likelihood of errors or minimize harm; however, they may need periodic updating and reinforcement. Low-leverage strategies, which aim to improve human performance, are easy and quick to implement; however, they are the least effective strategies for error prevention although frequently relied upon.

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Mortality Rate Can Be as High as 50% When Accidentally Administering TXA Intrathecally

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humans and have not been shown to be as effective as system-focused, high-leverage strategies. The risk-reduction strategies that are most effective for error prevention are forcing functions, barriers and fail-safes, automation, and computerization.[13] One such example of forcing function and fail-safe is the adoption of NRFit™ Neuraxial Connectors in Japan, which are designed to prevent misconnections and prevent wrong-route delivery of medications. This was made possible through advocacy with the Japan Ministry of Health, Labor, and Welfare.[14] Unfortunately, such efforts in the United States were met with resistance.[15]

Applying ISMP's hierarchy of the topmost effective risk-reduction strategies of using barriers and forcing functions is appropriate for TXA-associated intrathecal errors. This would involve restricting or eliminating TXA vials/ampules and only allowing manufacturer-prepared ready-to-administer TXA 1,000 mg per 100 mL bags or pharmacy-prepared IV bags. This strategy would likely create a constraint to avoid the look-alike problem with local anesthetic and TXA vials or ampules.

Removing vials of medications that cause patient harm from patient care areas is not a new concept. In the 1990s, concentrated potassium chloride vials were commonly stocked and readily available on patient care units. After the vials were found to have caused patient deaths, a national movement began that only potassium chloride in a diluted form should be allowed in patient care units.[16]

MEDICAL-LEGAL PERSPECTIVE

Medical malpractice claims arising from medication mix-ups, such as the one described in the case study above, are indefensible from a standard-of-care perspective. In addition to targeting the responsible clinicians, plaintiff's attorneys commonly assert negligence claims against facilities. This is particularly true when evidence or testimony comes to light to suggest the medication error was a consequence of the facility prioritizing labor efficiencies or other cost-saving measures over patient safety. These objectives are shortsighted and can lead to outcomes that harm both patients and the facility's bottom line. When medication errors result in catastrophic injuries, such as brain damage or death, patients and their families commonly seek millions of dollars in damages, particularly when patients require ongoing medical care or are unable to return to work.

In additional to civil litigation, clinicians who are responsible for medication administration errors may become the subject of licensing board investigations and criminal charges. While each board operates under its state's laws and regulations, some practice acts empower licensing authorities to pursue formal disciplinary action against clinicians in the wake of medication errors. At the facility level, medication errors can result in scrutiny from regulators and accrediting bodies, which can have significant implications from both financial and reputational standpoints.[17]

The need to report near misses and medication errors and to review systems issues at the department and hospital level in a nonpunitive manner cannot be overstated. In addition, having a system in place to provide appropriate confidential peer support when an event occurs will reduce the long-term negative impact that exists with a second victim.[18] Since peer review protections are generally established under state law, a hospital's ability to facilitate a meaningful analysis of these problems largely depends on its geographic location. In states lacking adequate protections, policymakers should pursue the adoption of laws that will enable facilities to implement appropriate, confidential peer-review practices so clinicians are free to review and discuss clinical care without fear of information being used against them during litigation. These efforts mitigate reoccurrence of adverse events, encourage reporting, and improve patient outcomes.[18]

MANUFACTURER'S PERSPECTIVE

To identify potential solutions, it is important to understand the complexity that results from the large and diverse number of suppliers for a particular product, including the variability in product appearance from one manufacturer to another. According to IQVIA (formerly Quintiles and IMS Health Inc.) data, currently, there are 13 companies that manufacture TXA for the U.S. market. The TXA presentation consists of vials (81.5%), premixed bags (16.9%) and ampules (1.6%). Eight companies manufacture bupivacaine, mostly in vials (98.7%) with some ampules (1.3%).[19]

While this diversity helps ensure a robust supply of these drugs, it also creates the potential for variability that can lead to product look-alikes. Manufacturers can incorporate an understanding of how drugs are stored into their packaging and labeling decisions, particularly in cases where products are stored together that are inherently higher risk, such as the combination of TXA and bupivacaine.

Another way manufacturers can help improve medication safety is by offering ready to administer (RTA) products. At the 2010 APSF Stoelting Conference on Medication Safety, manufacturer-prepared RTA products were not as prevalent as they are today. With the recent availability of manufactured RTA TXA 1,000 mg per 100 mL bags, implementing the APSF and ISMP recommendation to utilize preprepared dosage forms is a realistic and achievable means to prevent future TXA-bupivacaine errors.[20] Use of RTA products is recommended by major scientific and regulatory organizations including the Joint Commission.[21-22] Premixed bags and prefilled syringes do not require assembly at the point of care, which eliminates medication preparation steps where errors can occur.[21-22] In addition, FDA-approved manufacturer-prepared RTA products contain all required information on the manufacturer label and a barcode to help verify the proper drug and dose prior to administration, promoting safe medication delivery.[23-24] The FDA has a rigorous approval process for manufacturers seeking to introduce combination products

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Using Ready-to-Administer Products Can Reduce Medication Error

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integrating drugs and delivery systems. While a select number of manufacturers have this manufacturing capability, the growing segment of RTA products signifies a pivotal advancement in medication delivery, offering enhanced safety measures.

PREVENTING MEDICATION ERRORS

Providing forcing function and barriers as discussed above in having TXA available only in a premixed bag rather than in a vial form in the perioperative environment is the single most effective measure to reduce the incidence of wrong drug-wrong route TXA-bupivacaine errors. ISMP has included safeguards against wrong-route errors with TXA in the 2024–2025 ISMP Targeted Medication Safety Best Practices.[25] Some of the recommendations are listed below.

SYSTEM SAFEGUARDS

- Use barcode-assisted medication safety checks, if available, when preparing and prior to administering medications in surgical and obstetrical areas.
- Develop protocols to use premixed intravenous (IV) bags of TXA or pharmacy-prepared infusion bags to prevent mix-ups.
- Foster culture of safety
- Maintain a high level of vigilance when these two medications are given during a case.
- Meet with key stakeholders to review their workflow when ordering and administering TXA to ensure safe practices.
- Evaluate workload to ensure workload pressures will not result in unsafe workarounds and practices.
- Report near misses and unsafe medication practices.
- Conduct regular reviews and discussions of medication events and close calls reported in your institution.

CONCLUSION

Wrong drug-wrong route medication errors involving TXA and bupivacaine will continue to harm patients unless effective change is made. Regulatory authorities have the ability to work with stakeholders and impart this change. We have provided insight from multiple stakeholders with a commitment to help foster this change.

The authors of this article believe that TXA is a necessary and a beneficial medication for many surgeries and should continue to be available in the perioperative areas. However, TXA vials or ampules should be removed from the perioperative areas and RTA 100 mL bags from either the manufacturer, 503 B compounding facility, or institution's pharmacy should be the sole TXA dosage form available in the perioperative areas. The cost of a premixed bag may vary by regions, contracts, discounts, group purchasing organizations, and suppliers, and this cost is inconsequential when compared to the cost of a medication error involving significant morbidity and mortality. The time to act is now.

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Tricia Meyer is a speaker for Eagle Pharmaceutical and has consulted for Heron. The remaining authors have no additional conflicts of interest.

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Intraoperative Hypotension: A Public Safety Announcement for Anesthesia Professionals

by Amy Yerdon, DNP, MNA, CRNA, CNE, CHSE; D. Matthew Sherrer, MD, MBA, FASA, FAACD; and Desireé Chappell, MSNA, CRNA, FAANA

A common request from patients to anesthesia professionals is to "take good care of me." While we may confidently reply, "I will," many anesthesia professionals may not be aware of the growing body of data relating intraoperative hypotension (IOH) with patient morbidity and mortality. Mounting evidence supports an association between IOH and negative postoperative outcomes, most significantly acute kidney injury (AKI), myocardial injury after non-cardiac surgery, and mortality.[1-9] Recent studies also show associations between IOH and delirium, stroke, and readmissions.[1,4,9-11] The complications associated with IOH have far-reaching consequences for patients and the health care system. Acute kidney injury alone is associated with the development of further complications including stroke, myocardial injury, chronic kidney disease, and both in-hospital and one-year mortality, as well as increased length of stay, health care resource utilization, and health care costs.[4,12,13] Anesthesia professionals may be unaware of these alarming outcomes especially if they do not receive postoperative outcomes data. Evidence suggests that we must reduce IOH to avoid patient harm.

Intraoperative hypotension can be defined as the blood pressure (BP) below a "safe threshold" leading to hypoperfused organs.[1-9] The incidence of IOH varies depending on the definition used, which can involve both a reduction in blood pressure as well as the duration of the reduction. One study assessed the relationship between IOH and the outcomes of AKI and myocardial injury.[2] They evaluated both a relative reduction from baseline (i.e., 20% below preoperative BP) and an absolute threshold to define IOH. They found that absolute and relative thresholds had comparable ability to discriminate patients with myocardial or kidney injury from those without, thus suggesting an absolute threshold can be used. Mean arterial pressures (MAP) < 65 mm Hg lasting one minute were associated with an elevated risk of AKI and myocardial injury.[2] The risk of developing AKI and myocardial injury increased with a longer duration of IOH.[2] This discovery led to the definition of IOH as a MAP < 65 mm Hg for at least one minute.[2]

A review of available literature on IOH published from 2017 until late 2022, combined with relevant recent studies suggests that the most common definitions of IOH are any MAP < 65 mm Hg[1,4,6,10,14-18] or a MAP < 65 mm Hg for at least one minute.[8,10,19-26] Using this absolute MAP threshold, IOH is surprisingly common. A recent retrospective observational multicenter study of over 22,000 patients reported 88% of noncardiac surgery patients experienced at least one episode of IOH with a mean duration of 28.2 minutes (Table 1).[27] The authors noted significant practice variation in IOH management across the eleven medical centers studied, suggesting differences in provider tolerance of IOH.[27]

Table 1. Comparison of IOH incidence between four studies

IOH INCIDENCE (MAP < 65 MM HG)					
	Gregory[1]	**Chiu[6]**	**Saasouh[30]**	**Shah[27]**	
Patients (n)	368,222	32,250	127,095	22,100	
Duration of IOH	At least one reading	At least one reading	≥ 15 min	≥ 1 min	≥ 10 min
Patients with IOH	19.3%	*	29%	88%	31%
Mean duration (min)	22	23.9	36.2	28.2	

*Not indicated in the study.

The Centers for Medicare and Medicaid Services (CMS) recognizes a new IOH quality measure, defined as a MAP < 65 mm Hg for greater than 15 minutes, as a criterion in the Merit-Based Incentive Payment System (MIPS).[28] A lower overall IOH measure score indicates less time spent under the defined MAP.[28] The MIPS score is totaled based on performance measurements of quality, improvement activities, promoting interoperability, and cost. The ePreop[31] measure is one of six anesthesia measures that can be submitted for the quality portion of the MIPS score.[28,29] The final MIPS score determines the payment adjustment applied to Medicare Part B claims.[29] A recent study using the CMS MIPS definition of IOH found the incidence of IOH in community anesthesia practice was 29% in noncardiac procedures.[30] This study found varying IOH incidence among clinicians, adding to the body of evidence supporting the reduction of practice variation in IOH management.[14,30,31] The authors considered IOH a modifiable risk and suggested pursuing quality improvement initiatives to reduce IOH tolerance.[30]

A common theme, regardless of the IOH definition, is that more severe degrees of hypotension and a longer cumulative hypotension duration are associated with increased risk of patient morbidity and mortality. Numerous studies show a MAP < 65 mm Hg for extended periods of time, or any period of a MAP ≤ 55 mm Hg, is associated with a greater risk of negative outcomes.[1-3,9,16,17,32] Consequently, we simply ***should*** minimize the occurrence, severity, and duration of IOH.

Reducing IOH may be challenging when using traditional intermittent oscillometric BP (IOBP) monitoring with an arm cuff. Concerns with IOBP monitoring include delayed or missed detection of BP changes or hypotensive episodes, inaccuracy during hemodynamic extremes, and overestimation of BP during hypotension resulting in more severe episodes than realized.[19,33] The potential for missed hypotensive events with IOBP monitoring varies depending on the frequency of measurements chosen or the default setting on the physiologic monitor. One recent study found the most common frequencies of IOBP measurements chosen were every two to five minutes.[25] These infrequencies allow for the undetected accumulation of hypotensive minutes between measurements, which may increase the patient's risk of experiencing harm and may have been minimized with continuous monitoring.[15,19,25]

New studies support using continuous BP monitoring, touting several benefits over IOBP, including less BP variability,[16] improved hemodynamic stability,[33] detection of hypotensive episodes missed by IOBP,[19] earlier recognition and treatment of IOH,[15,25] and overall reductions in IOH.[15,19,25,33] Continuous BP monitoring may be accomplished invasively with intra-arterial BP monitoring, but comes with risks, such as infection, nerve damage, thrombus, and pseudoaneurysm.[25] Continuous noninvasive BP monitoring with a finger cuff avoids the risks

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associated with invasive arterial lines while providing comparable MAP values.[25,33] Limitations of this technology include additional costs compared to intermittent oscillimetry and the potential for less accuracy in elderly patients or those with atherosclerosis.[25,34,35] The noninvasive finger cuff described in recent studies employs volume clamp technology using varying cuff pressure over the finger arteries to maintain a constant volume.[25,33] The finger arterial BP is reconstructed to an arterial waveform, allowing for pulse wave analysis, which provides advanced hemodynamic variables (e.g., stroke volume, cardiac output, stroke volume variation) useful for determining the cause of IOH.[25] A noninvasive finger cuff can be an appropriate option for continuous BP monitoring when arterial blood samples are not needed during the surgical procedure.[33]

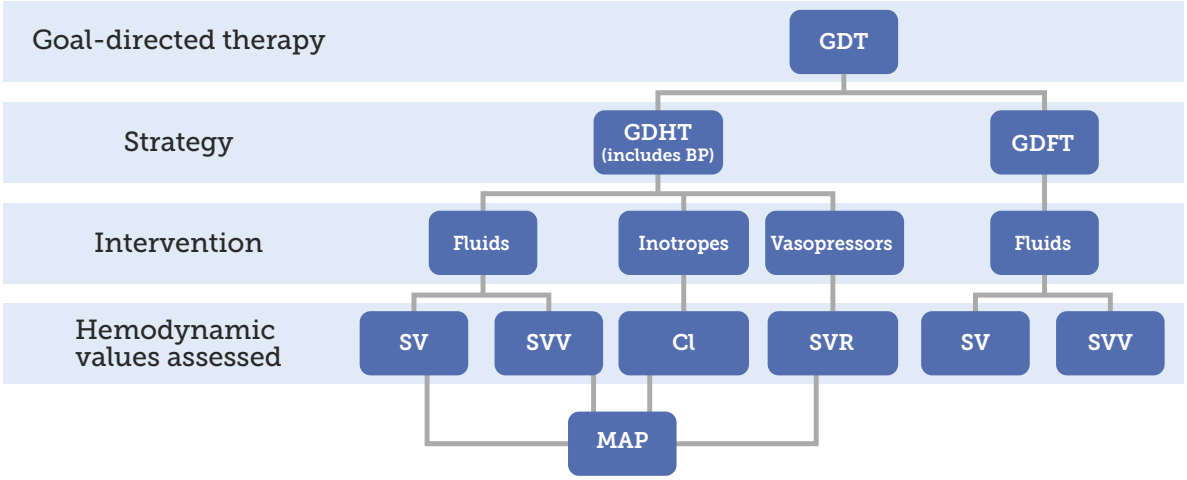

Figure 1. Depiction of the components of a GDT strategy, resulting from a conceptual merging of GDHT and GDFT strategies, along with hemodynamic values guiding specific targeted interventions.

GDT: Goal-directed therapy; GDHT: Goal-directed hemodynamic therapy; GDFT: Goal-directed fluid therapy; SV: Stroke volume; SVV: Stroke volume variation; CI: Cardiac index; SVR: Systemic vascular resistance; MAP: Mean arterial pressure

Inappropriate fluid and vasopressor management may cause organ hypoperfusion and lead to end organ injury, emphasizing the importance of intentional strategies to avoid these problems.[1,3,6,7,12,32] Ariyarathna et al. described a relationship between high vasopressor use and postoperative AKI, independent of IOH.[12] Another study suggested that implementation of fluid restriction with their ERAS protocol was associated with significant increases in postoperative hypotension.[31] In this study, those with postoperative hypotension also experienced significant IOH and received less total intraoperative fluids. In a recent five-year multicenter retrospective study among Multicenter Perioperative Outcomes Group (MPOG) institutions of over 32,000 abdominal surgery patients, increased AKI rates were observed despite an overall IOH reduction.[6] Additionally, they discovered a decline in intraoperative fluid administration and increased vasopressor use, both of which were associated with increased AKI incidence. When crystalloid administration increased from one to ten milliliters per kilogram per hour (mL/kg/hr), they observed a 58% decrease in AKI risk. These poignant findings support the physiologic concept that relying on vasopressors to maintain BP while minimizing fluid administration may diminish already compromised splanchnic and renal perfusion, and potentially cause iatrogenic harm in the forms of ileus, postoperative nausea and vomiting, surgical site infections, and AKI.[6,7,12,36]

The causes of IOH are multifactorial and include reduced myocardial contractility, vasodilation, hypovolemia, bradycardia, extrinsic compression of heart chambers (e.g., pericardial effusion or pneumothorax), or a "mixed type" explained by multiple hemodynamic alterations.[8,18]Using monitors that provide advanced hemodynamic variables (e.g., stroke volume, cardiac output, stroke volume variation) may be beneficial for preventing, diagnosing, and treating hypotension.[8] Interventions may then be targeted at the root cause of IOH using a goal-directed therapy (GDT) strategy, rather than simply improving the MAP number displayed on the physiologic monitor.

The term GDT may be conceptualized as an umbrella term describing the optimal administration, at the most appropriate time, of fluids, inotropes, and vasopressors using an advanced hemodynamic monitor. Intraoperative interventions within a GDT strategy are aimed at specific endpoints or goals to optimize tissue oxygen delivery and prevent organ hypoperfusion (Figure 1).[5,17] The hemodynamic monitor is used to assess patient responsiveness to these interventions. Goal-directed fluid therapy (GDFT) was the first and the most commonly known iteration of the modern GDT concept. The advanced hemodynamic monitor is used to identify preload dependence, aid in the decision to treat with fluid bolus(es) to optimize a patient's position on the Frank-Starling curve, and then assess for fluid responsiveness.[7,17] The 2020 Perioperative Quality Initiative (POQI) consensus statement on fluid management affirmed the safest and most effective method for guiding fluid therapy is to assess for fluid responsiveness.[7] Further, optimizing SV with fluids leads to better gastrointestinal perfusion and fewer complications, suggesting the importance of adequate circulating volume and gut perfusion.[36] Goal-directed hemodynamic therapy (GDHT), another component of GDT, improved the original GDFT strategy by incorporating the maintenance of MAP to avoid IOH into the protocol.[17] GDT strategies incorporating hemodynamic optimization are associated with significant reductions in morbidity and mortality.[5,11,32] Figure 1 depicts the modern GDT concept encompassing the components of its first iteration of GDFT, then GDHT, which incorporates the entire picture of perfusion.

Multiple studies using advanced hemodynamic monitoring with a GDT protocol aimed at determining appropriate treatments specific to the cause(s) of IOH and optimizing hemodynamics have shown significant reductions in postoperative complications.[5,11,24,32] One study found using a GDHT protocol reduced complications and hospital length of stay (LOS) in low to moderate-risk surgery patients in the landmark FEDORA trial.[5] Another study included high-risk patients undergoing major surgery also used a GDHT protocol. This trial resulted in

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IOH is a Serious Public Health Issue

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a reduced risk of postoperative organ dysfunction.[32] One strength of this later study was the protocolized hemodynamic algorithm used for guiding fluid administration to optimize stroke volume, thereby maintaining intravascular volume and organ perfusion pressure, and protecting against hypoperfusion. In a study of elderly patients undergoing spine surgery, the use of a GDT protocol resulted in less IOH, postoperative nausea and vomiting, and delirium in the GDT group compared to the control group.[11] Additionally, other studies using a GDT protocol reported reductions in IOH, further supporting the use of protocols to guide care aimed at targeting IOH causes.[21,23,24] GDT has been shown to benefit a range of patients, including low, moderate, and high-risk patients.

In the 2021 article on the association of IOH and adverse outcomes, IOH was described as a **"serious public health issue"** that is not permissible for any age group and for any time.[1] Due to the size of the population at risk of IOH exposure, the authors urgently recommended future research focusing on IOH prevention. Traditional hemodynamic management relies on reactively treating IOH after it occurs, which is too late as it is already causing organ damage.[20] In a 2021 *APSF Newsletter* article, Sessler alluded to the benefits of ***predicting*** IOH with recent technological advancements based on artificial intelligence and machine learning.[37] Numerous studies have since been published validating the use of new technology for accurately predicting and reducing IOH.[8,20-23,26] One such available technology for predicting the likelihood of impending IOH, along with its root cause, utilizes a parameter called the Hypotension Prediction Index (HPI). HPI provides a unitless number on a scale from zero to 100, indicating the probability that a hypotensive event will occur.[38] Using the information provided by the monitor regarding the underlying cause of the impending IOH allows the clinician to intervene appropriately with targeted treatments, thereby avoiding IOH. In a systematic review of randomized controlled trials evaluating the ability of HPI to reduce IOH, authors stated HPI has the potential to reduce the occurrence, duration, and severity of IOH during noncardiac surgery, but emphasized the importance of protocolized adherence to management when using the technology.[22] This finding further supports the role of reducing practice variation in reducing the incidence of IOH.

Anesthesia professionals strive to provide excellent anesthetic care for their patients but may be unaware of the potentially detrimental consequences of their hemodynamic management. As Gregory and colleagues powerfully stated, IOH is a **"public safety issue,"** which must be minimized.[1] A step by step approach may help to achieve this goal. Figure 2 lists suggested next steps from the authors of this article incorporating recently published consensus recommendations and best practices from the APSF.[39]

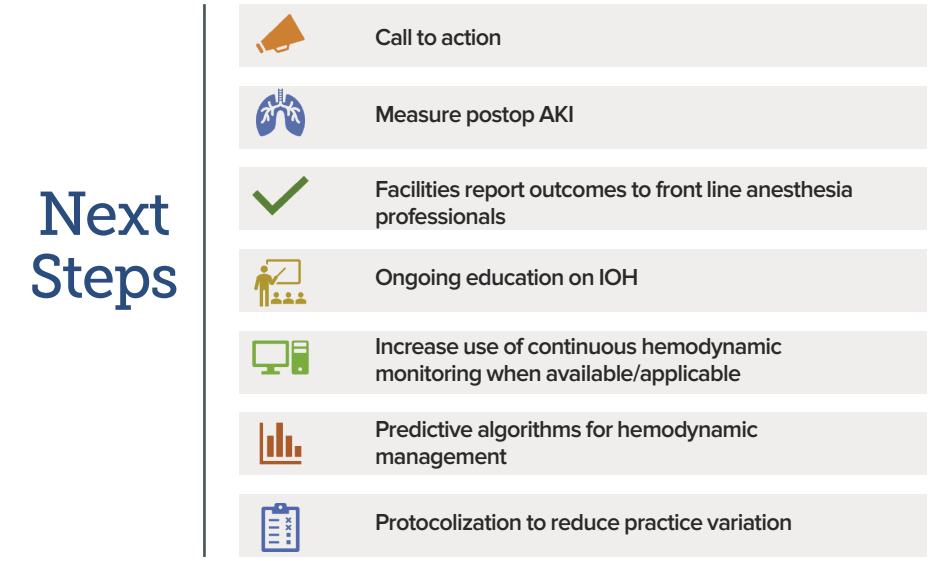

Figure 2. Suggested next steps for anesthesia professionals. The figure incorporates recently published consensus recommendations and best practices from the APSF to help achieve the goal of minimizing IOH and associated patient harm.[39]

AKI: acute kidney injury; IOH: intraoperative hypotension.

We must acknowledge that IOH is a common problem and raise awareness among colleagues through education and by monitoring and tracking postoperative outcomes such as AKI and myocardial injury after noncardiac surgery. We should monitor continuously with advanced hemodynamic technologies where pertinent to avoid undetected IOH. We must appropriately manage hemodynamics by balancing the circulation to correct the problem (e.g., GDT protocol), rather than treating the number on the monitor with vasopressors. IOH is a modifiable risk that we simply should not continue to tolerate.

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An Evolving Framework for Using Big Data Tools and Machine Learning to Enhance Perioperative Quality Improvement, Research, and Patient Safety

by Michael R. Mathis, MD; Robert B. Schonberger, MD, MHCDS; Anthony L. Edelman, MD, MBA; Allison M. Janda, MD; Douglas A. Colquhoun, MB ChB, MSc, MPH; Michael L. Burns MD, PhD; and Nirav J. Shah, MD

In an era of near-complete adoption of electronic health records (EHRs) and coalescence of health data across departments and institutions, a growing recognition of practice variation has emerged. Perioperative care is no exception, with recent studies demonstrating wide institution-level variation in practices such as anesthetic techniques employed,[1] medications administered,[2,3] and operating room staffing models used.[4] In some cases, practice variation is warranted—as explained by factors such as subspecialty training, local health resource constraints, and informed expectations of patients. Yet, in other cases variation is unexplained or unwarranted, and possibly attributable to a lack of practice benchmarking, suboptimal hospital resource allocation, or lack of precision care tailored to individual patient needs.[5,6]

In some cases, such practice variation may be associated with worse outcomes, including anesthesia professional staffing ratio practice patterns,[4] hospital level compliance with safety practices,[7] and failure to rescue rates.[8]

To address unexplained or unwarranted variation, modern quality improvement (QI) and research initiatives increasingly seek out multicenter learning-health systems approaches, integrating comparative effectiveness evidence drawn from practice variation across centers to develop performance benchmarks and quality measures.[9,10] With strategic multicenter infrastructures in place, such benchmarks and quality measures can in turn be disseminated across participating institutions to rapidly iterate upon evolving best practices and enhance patient safety and health care value.[11,12] One learning health system infrastructure relevant to perioperative care is the Multicenter Perioperative Outcomes Group (MPOG), which we cover in this article to illustrate (i) approaches necessary for integrating perioperative EHRs for research and quality improvement (QI); (ii) big data tools which can be used to effectively harness large volumes of perioperative health data amassed; and (iii) the value proposition of creating community sharing research and quality measure outputs to advance perioperative care and patient safety. Finally, with the rise of artificial intelligence and machine learning approaches offering new opportunities for enhancing health information gathering and clinical decision-making, we describe core challenges to successful, sustained implementation of artificial intelligence/machine learning methods and approaches to address such challenges.

PRINCIPLES OF A LEARNING HEALTH SYSTEM GUIDED BY PERIOPERATIVE DATA: THE MULTICENTER PERIOPERATIVE OUTCOMES GROUP (MPOG)

A Learning Health System (LHS) has been defined as one "in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the health care delivery process and leads to continual improvement in care."[13] MPOG aspires to be a learning health system focused on perioperative care that addresses continuously rising standards for QI, research, and patient safety (Figure 1). MPOG was launched in 2008 by several academic centers interested in using their newly implemented electronic anesthesia recordkeeping systems for multicenter observational analyses. However, it soon became clear that this same dataset, with appropriate governance and collaboration, could be the foundation of a learning health system where MPOG data generates knowledge. This knowledge leads to practice change, and practice changes lead to new data. The flywheel effect of this approach has now led to the participation of nearly 100 hospitals in the MPOG group. In turn, MPOG has developed tools to extract, ingest, clean,

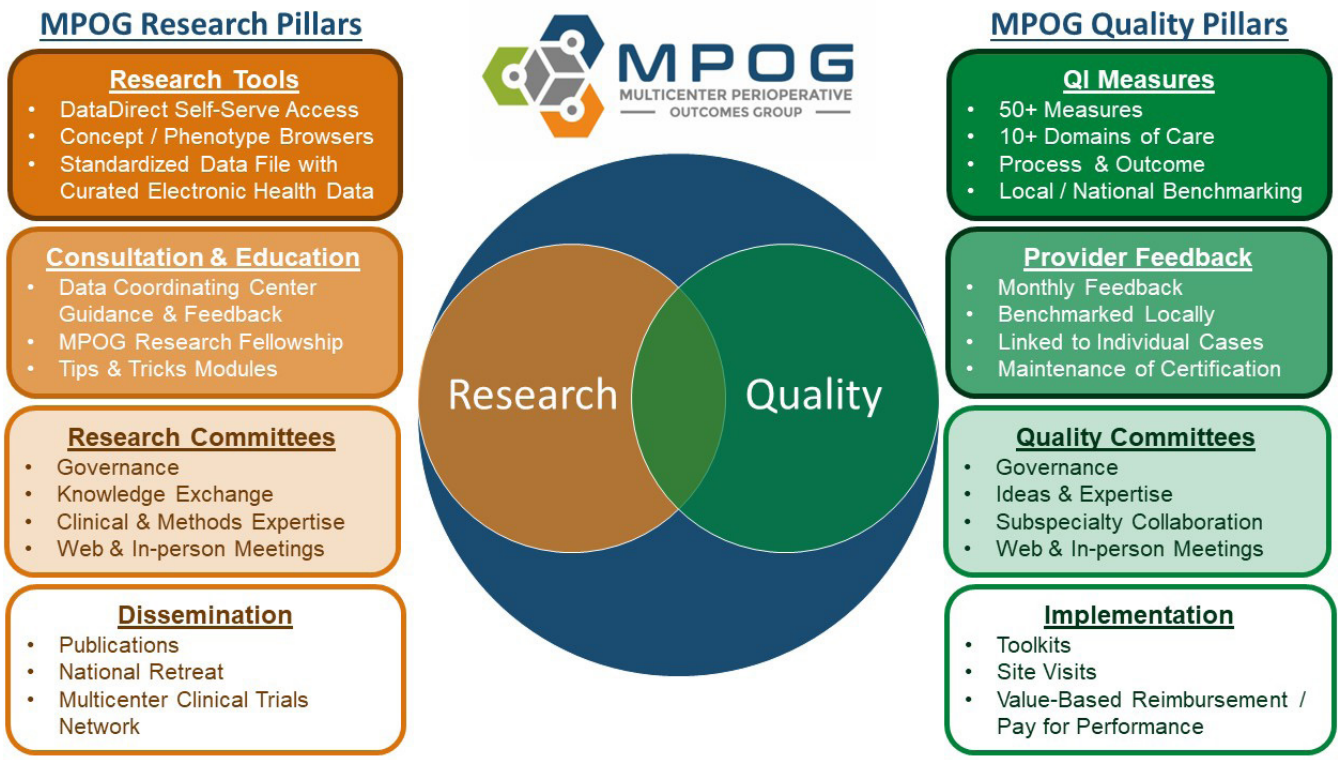

Figure 1: Pillars of Multicenter Perioperative Outcomes Group (MPOG) Research and Quality Improvement.

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MPOG has developed programs and tools to analyze big data

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and analyze these data for a variety of research, QI, and education-related uses. The minimum dataset submitted by each institution includes physiologic, medication, text notes, staffing, key events, and fluid input and output data during the perioperative period. These markers are all derived automatically from institutionally mapped data within existing anesthesia medical records and are largely agnostic to the specific EHR vendor being used at each institution. Additionally, preoperative history and physical information, laboratory results, and administrative data such as Current Procedural Terminology (CPT) codes, discharge diagnoses, and hospital mortality data are included.

EHR data are highly variable across institutions. As a result, a foundational component of MPOG is the methodology for translating EHR data across participating sites into pre-computed, validated phenotypes usable for research and QI.[14] This rigorous process involves applying algorithms to integrate combinations of all the data types within MPOG to generate more reliable clinical inferences. These inferences serve as building blocks that enable both researchers to conduct analyses, and QI leaders and clinicians to understand variation in care patterns. Examples of phenotypes that are essential components of MPOG research and QI include anesthesia technique, American Society of Anesthesiologists physical status, and patients' smoking status. In each of these cases, there are thousands of ways these data are documented across sites, and software algorithms developed by MPOG translate the data into interoperable phenotypes.

Table 1: Quality Improvement Programs within the Multicenter Perioperative Outcomes Group.

PROGRAM	DESCRIPTION
QI Measure Development	MPOG has developed over 60 process and outcome measures across several anesthetic, subspecialty, population, and public health domains. These measures are approved and reviewed at the Quality Committee, and the specifications made available publicly for all to review and use.[15]
Practice level feedback	Our QI Reporting Tool enables practice leadership to visualize measure performance that is benchmarked locally and nationally, and understand variation in care by patient, case, and provider (Figure 2). Users can probe from health system-level performance to a single intraoperative anesthetic record or group of similar records to identify exemplars of practice or opportunities for improvement.
Individual provider feedback	MPOG sends monthly feedback via email to anesthesia professionals on QI measures selected by practice leaders for their institution. Performance on these measures is benchmarked locally, and can be linked to individual anesthetic records to enable the reflection that can more effectively lead to changes in practice.
QI Toolkits	To help remove barriers to education and implementation of QI initiatives, the MPOG Coordinating Center has developed toolkits that summarize the available evidence for our measures and provide implementation tips that can be applied locally. Toolkits exist for several domains of anesthesia care, including postoperative nausea and vomiting prevention, transfusion management, prevention of kidney injury, prevention of lung injury, and environmental sustainability.[16]
Quality Collaborative Meetings	To reinforce and discuss the application of these quality measures, feedback platforms, and toolkits, MPOG organizes multiple collaborative meetings attended by anesthesiologist QI champions and surgeon collaborators.

MPOG TOOLS FOR TRANSFORMING PERIOPERATIVE EHR DATA INTO KNOWLEDGE AND ACTION FOR ENHANCING PATIENT SAFETY

MPOG has developed programs and tools to analyze big data and enable inferences for nuanced and meaningful QI and research projects aimed at improving patient safety.

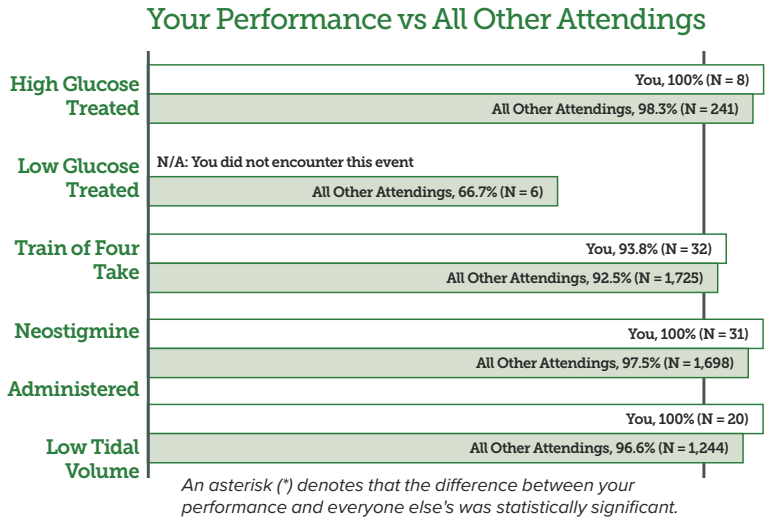

Figure 2: Individual Provider Feedback on Perioperative Quality: Personalized Performance Emails.

MPOG's QI mission is governed by its Quality Committee, composed of anesthesia professional QI champions for each participating site. This committee approves and maintains quality measures reflecting the best available evidence with an established plan to revisit QI measures at regular intervals to accommodate the field's expanding and evolving knowledge base. Ideas for new QI initiatives are generated from this committee as well as subspecialty subcommittees focused on pediatric, obstetric, geriatric, and cardiac anesthesia, each composed of quality champions and domain experts from participating institutions. These committees foster open discussions, collaboration, and the sharing of best practices and lessons learned.

In order for members to enact change at their institutions, MPOG has developed a series of programs built upon the computed phenotypes foundation. These programs include QI measure development, practice level feedback, individual provider feedback, QI toolkits, and quality collaborative meetings as described in Table 1. Further details describing all QI measures can be found at https://spec.mpog.org/Measures/Public. Individual provider performance can be tracked and feedback can be provided to individuals (Figure 2).

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EHR Data Are Highly Variable Across Institutions

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To complement its QI mission, MPOG's research mission is governed by its Research Committee, which coordinates clinical research efforts of MPOG by reviewing submitted proposals and tracking the progress of ongoing projects. This committee, composed of MPOG principal investigators from each participating site, evaluates all MPOG research proposals, provides crucial guidance on hypotheses and methodology, and ensures the scientific appropriateness of clinical research using MPOG data prior to a project's approval. To enable meaningful research using MPOG data, the group has built several programs and tools to leverage the Registry. These programs include regular research committee meetings and an annual MPOG Retreat, as well as software tools (e.g., DataDirect®, Ann Arbor, Michigan) to develop research cohorts and streamline research queries.

PERFORMANCE IMPROVEMENT WITHIN THE STATE OF MICHIGAN

In the state of Michigan, MPOG is part of a Blue Cross Blue Shield of Michigan funded QI program, which functions as a learning health system.[17] This program funds QI groups across a range of specialties and health conditions.[18] Through the mechanisms described above, unblinded performance reviews, multispecialty collaborative meetings, and payor-driven financial incentives lead to substantial improvements in care. These are evidenced by improvements in important anesthetic care domains such as glycemic and temperature management, as well as achieving more cost-effective care for hospitals participating in this program (Table 2).[19]

RESEARCH INITIATIVE: ASSESSMENTS OF MULTICENTER PRACTICE VARIATION AND PERIOPERATIVE CARE STRUCTURES

Given the breadth of perioperative practice variation across clinicians and sites, important research findings of MPOG have included studies which quantify the degree to which practice patterns are explained by the clinician or institution, rather than the patient or surgery. Such practice variation, potentially indicative of clinician training, personal practice preferences, or institution-level structures of clinical care and infrastructure, has been leveraged to study impact on patient outcomes. In some cases, practice variation—including anesthesia professional staffing ratios, hospital level compliance with safety practices,[7] and failure to rescue rates[8]—is associated with worse outcomes; whereas in other cases a lack of association exists with adverse outcomes, including overlapping surgeries by an attending surgeon[20] or surgeries in which the surgeon operated overnight the day prior.[21]

Table 2: Multicenter Perioperative Outcomes Group Examples of Quality Improvement Impact.

QI INITIATIVE	PROGRAM AND RESULTS
Prevention of hypothermia	MPOG launched an initiative across the state of Michigan in 2018 to reduce intraoperative hypothermia. Process measures determining use of active warming and appropriate temperature monitoring and outcome measures determining rates of hypothermia were developed. MPOG sites in Michigan reduced hypothermia at the end of case from 10.8% to 5.6% from 2018 to 2023.
Treatment of hyperglycemia	MPOG launched an initiative in 2015 to improve management of hyperglycemia. Through measures determining appropriate checking and treatment of hyperglycemia, MPOG sites in Michigan participating in MPOG improved compliance for appropriate treatment of hyperglycemia with insulin from 59.7% in 2015 to 81% by 2023.

This is from data extracted from MPOG database 08/2023, and presented at the APSF conference, Las Vegas, 09/2023.

OPPORTUNITIES AND CHALLENGES INTRODUCED BY ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN PERIOPERATIVE CARE

Coinciding with the development of big data tools for processing electronic health record (EHR) data to perform multicenter research and QI, are opportunities to apply methods using artificial intelligence and machine learning to improve data quality, develop QI measures, and improve clinical care through predictive algorithm development. Given the complexities and granularity of perioperative EHR data, artificial intelligence/machine learning methods capable of handling large numbers of complex non-linear interactions across variables sometimes offer substantial advantages over classical statistical approaches. Yet, challenges exist to safe adoption of artificial intelligence/machine learning-based methods in perioperative learning health systems. These include (i) wide variations in the available clinician knowledge base regarding strengths and limitations; (ii) a need for clinical algorithm oversight and governance; (iii) the need to ensure fidelity of source data upon which artificial intelligence/machine learning algorithms are trained; and (iv) a systematic approach to recognizing and addressing biases potentially propagated in artificial intelligence/machine learning-based clinical decision support systems (Figure 3).

Related to clinician knowledge, artificial intelligence/machine learning education is being incorporated into medical curricula and continuing medical education opportunities in health care.[22] Related to algorithm governance and oversight, QI and patient safety efforts propose frameworks for committees to monitor artificial intelligence/machine learning models deployed within a health system.[23] With regard to data fidelity, approaches to diagnosing and remedying changes to EHR data quality ("dataset shift") are proposed,[24] focusing on maintaining closed-loop communication between frontline clinicians and algorithm governance committees, which may enhance patient safety by promoting awareness of model under-performance and thereby educating clinicians as to clinical contexts for which the prediction model can be relied upon versus disregarded. Finally, as algorithmic bias concerns remain, opportunities to address differential model performance across varying clinical subgroups—particularly when racial, ethnic, and sex-based,[25]—include explicitly examining artificial intelligence/machine learning model performance in such subgroups.

CONCLUSION

Opportunities are ripe for coalescing perioperative EHR data across patients, clinicians, institutions, and regions to perform comparative effectiveness research and improve the quality and safety of anesthesia care. Perioperative learning health systems equipped with big data tools with appropriate leveraging of novel artificial intelligence/machine learning-based methods provide a platform for clinician communities to share data, exchange ideas, and disseminate evolving best practices within a learning health system.

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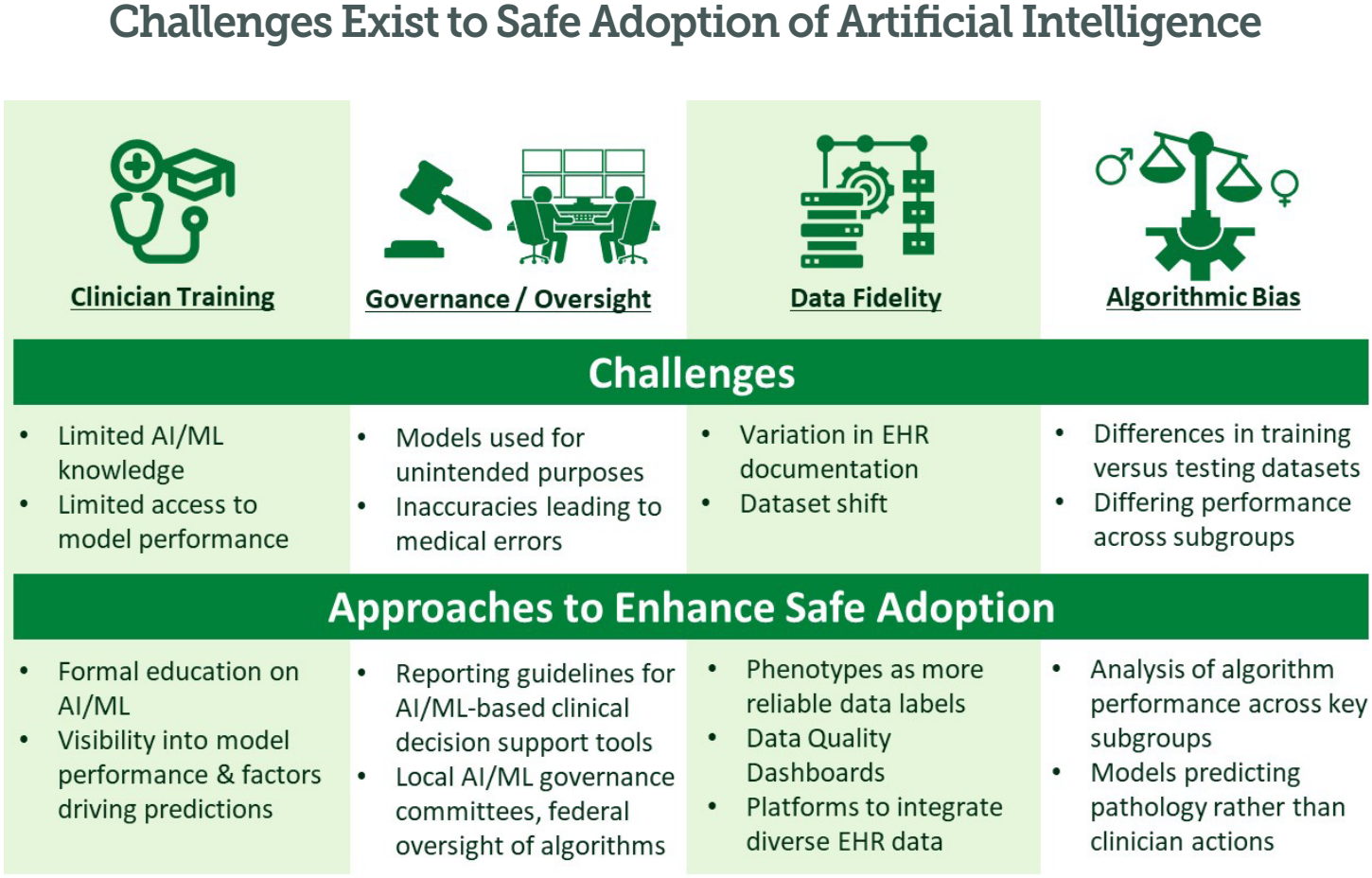

Figure 3: Considerations for Safe Adoption of Artificial Intelligence (AI) and Machine Learning (ML) into Perioperative Care.

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Artificial Intelligence/Machine Learning Provide Platform for Clinicians to Share Data Regarding Best Practices

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We know that workplace violence is toxic—impacting culture, teamwork, clinician well-being and patient safety. A 2021 Stoelting Conference Cross-sectional Survey showed 71.6 % of perioperative respondents (anesthesiologists, certified anesthesia assistants, certified registered nurse anesthetists, OR nurses, recovery room nurses, surgeons) report experiencing nonphysical workplace violence.

APSF is pleased to release three trigger-video workshop modules on workplace violence focusing on: Discrimination, Physical Aggression and Incivility. These videos, along with their companion facilitation guides are freely available through the APSF website. Alex Hannenberg, MD, Della Lin, MD, and Randy Steadman, MD, collaboratively produced these modules with filming logistics provided through UCLA's Simulation Center.

Utilizing these workshop modules can open dialogue, jump start, and be integrated into existing workplace violence programs.

The videos and facilitation guides can be found at https://www.apsf.org/videos/workplace-violence/.

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Saturday, October 19, 2024

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Opioid-Induced Respiratory Depression—Pediatric Considerations

by Tricia Vecchione, MD, MPH, and Constance L. Monitto, MD

Following surgery, respiratory depression can occur for a variety of reasons and results in potentially catastrophic complications.[1] One of the recurring causes of respiratory depression in the postoperative period is the perioperative use of opioids.[2] In light of this, institutions and professional societies, including the Anesthesia Patient Safety Foundation (APSF), have developed recommendations regarding patient monitoring[3,4] and published articles advocating that decisions regarding the appropriate level of postoperative monitoring be guided by preoperative assessment of patient-specific risk factors.[5] As with adults, perioperative respiratory complications occur in pediatric patients and constitute a common cause of postoperative adverse events.[6] However, children are not "little adults." Hence, extrapolating previously published guidelines and studies must be undertaken with caution.

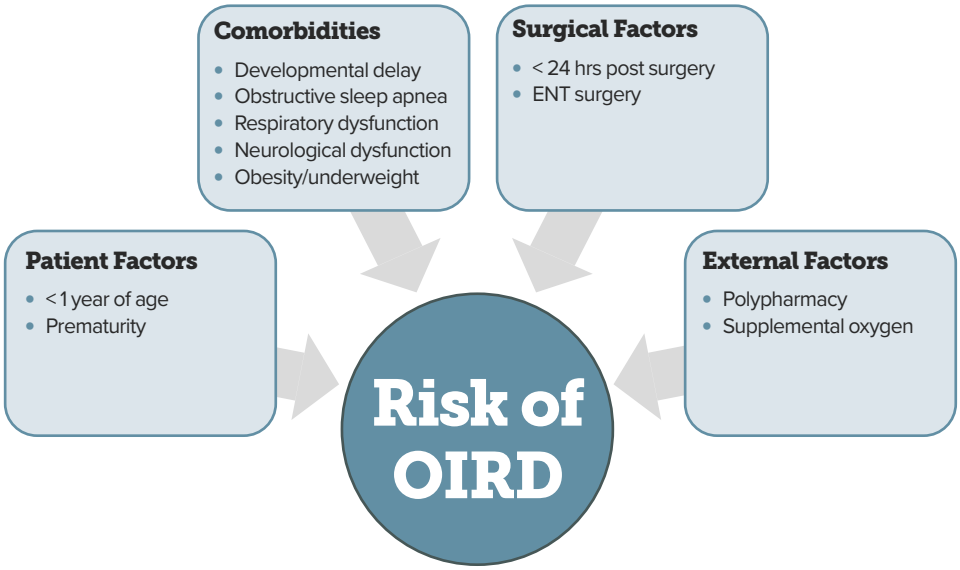

Figure 1. Summary of risk factors associated with increased risk of Opioid Induced Respiratory Depression {*OIRD) in children.*[4,10]

PEDIATRIC RISK FACTORS FOR OPIOID-INDUCED RESPIRATORY DEPRESSION

There is limited literature available addressing risk factors for opioid-induced respiratory depression (OIRD) in children. While comorbidities including diabetes mellitus and cardiac disease are significant risk factors for critical respiratory events in adults after parenteral opioid therapy,[7,8] given their low incidence in children, they are unlikely to be primary drivers in the pediatric setting. Instead, evidence from patient audits and data tracking administration of naloxone, a surrogate indicator of OIRD, has helped identify risk factors (Figure 1). For example, underlying respiratory disease and developmental delay have been identified as comorbidities that may play a role in increasing risk for pediatric OIRD.[9-11]

Another risk factor for OIRD in the pediatric population is young age. In a retrospective review of pediatric patients who required naloxone for critical respiratory events, increased incidence was associated with younger age as well as prematurity.[10] Increased risk may be attributed to physiologic differences regarding metabolism and excretion of opioids between young infants and older children and adults. For example, the half-life of morphine is prolonged and clearance is lower in newborns. Thus, depending on dosing, infants younger than one month of age may achieve higher serum levels that decline more slowly as compared to levels in older children and adults, putting them at elevated risk.[12]

The increased risk of postoperative respiratory depression with obstructive sleep apnea (OSA)[13] is also reported in children. Following tonsillectomy, children with severe OSA are more sensitive to morphine-induced respiratory depression and require less morphine than those with mild sleep apnea.[14] OSA is relatively common in pediatrics, occurring in 1–5% of children.[15] However, preoperative screening can be somewhat challenging. Polysomnography is the gold standard in diagnosis, but it is not available for most pediatric patients. There is no validated risk assessment questionnaire applicable to children of all ages; however, pediatric-specific risk factors and symptoms of OSA have been reported.[16]

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Experts Suggest Continuous Monitoring of Oxygenation and Ventilation for at Least 24 Hours Postoperatively in Pediatric Patients Who Receive Opioids

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Childhood obesity is also a risk factor for naloxone administration.[10] This may be attributed to the strong association between obesity and OSA or may reflect inaccurate dosing related to obesity. In contrast to adults, weight-based dosing is a common practice for many pediatric medications, but opiate dosing based on total body weight can cause dangerous respiratory depression. Therefore, dosing should be based on ideal or lean body mass.[17] Interestingly, in children, being underweight is a risk factor for respiratory events as well.[10]

Excessive sedation has been observed prior to opioid-related morbidity in a majority of children.[4] While the sedating effects of opioids in opioid-naive patients are well known, central nervous system (CNS) depression can be compounded by co-administration of anxiolytics, muscle relaxants, anticonvulsants, and other sedating medications. Such combinations can lead to life-threatening respiratory events and increased risk for naloxone interventions.[10] This is particularly important as co-administration of opioids and other CNS depressants has been reported to be common in pediatric practice with more than 40% of respondents allowing co-administration of these medications in a 2010 survey of pediatric pain management practice.[18] While practice may have changed in the intervening decade, given the recent focus on opioid sparing with multimodal analgesic regimens, this polypharmacy is unlikely to have decreased dramatically.

Following surgery, the highest risk for respiratory depression occurs within the first postoperative day. In fact, 75% of episodes in children who received naloxone for critical respiratory events were seen within the first 24 hours after surgery. Events occurred in patients who received opioids via the intravenous, oral, and neuraxial routes, suggesting no method of administration is intrinsically without risk.[10]

CURRENT RECOMMENDATIONS FOR MONITORING OF PEDIATRIC PATIENTS

To minimize the risk of respiratory depression, the APSF has long advocated that continuous electronic monitoring of oxygenation and ventilation, when supplemental oxygen is provided, be used to preemptively identify and potentially prevent OIRD.[3] While no studies specifically differentiate the monitoring requirements for pediatric patients, a consensus statement endorsed by the Society for Pediatric Anesthesia supports extra vigilance in the care of select patients, including neonates, children with OSA, and those with underlying neuromuscular diseases or cognitive impairment, which can impact respiratory muscle function and/or impede assessment of the patient's level of pain or consciousness. Furthermore, pediatric patients initiating opioid therapy, especially in the initial postoperative period, those who are receiving escalating doses of parenteral opioid, and those receiving opioids in conjunction with other CNS depressants are deemed worthy of increased vigilance.[4]

Expert opinion supports monitoring of pediatric patients receiving initial doses of parenteral opioids or opioids by patient-controlled analgesia (PCA), PCA by proxy, and/or constant infusion, specifically recommending continuous respiratory rate and pulse oximetry monitoring for the first 24 hours unless the patient is awake and actively being observed.[4,12] Previous research supports the utilization of more frequent continuous monitoring in children. In a 2010 survey study of pediatric pain management practice, respondents reported that continuous pulse oximetry monitoring was commonplace when PCA opioid was provided.[18] However, continuous monitoring of respiratory rate was less consistently utilized (Figure 2).

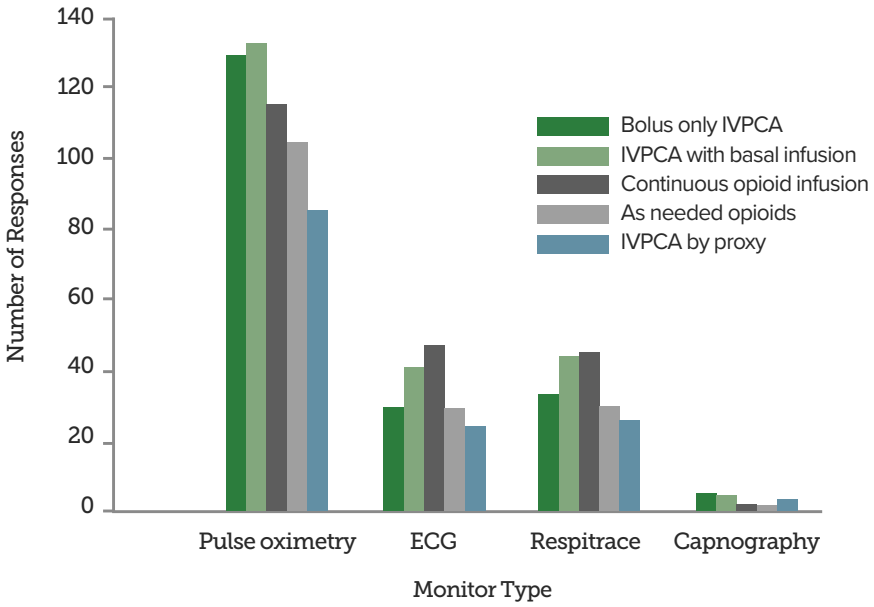

Figure 2: Type of patient monitoring used when opioids are administered to pediatric patients. (Total number of respondents who answered question, 149; total number of respondents who provided IV patient-controlled analgesia [IVPCA] by proxy, 95.) Ninety percent of respondents reported using pulse oximetry monitoring when patients were administered PCA. Electrocardiographic monitoring and capnography were always used in conjunction with pulse oximetry, whereas respiratory inductive plethysmography (Respitrace) was almost always provided in conjunction with pulse oximetry (>90%) but was occasionally used as the sole type of monitoring.[17] Reprinted with permission from Anesthesia & Analgesia *and Wolters Kluwer Health, Inc. Nelson KL, Yaster M, Kost-Byerly S, Monitto CL. A national survey of American Pediatric Anesthesiologists: patient-controlled analgesia and other intravenous opioid therapies in pediatric acute pain management.* Anesth Analg. *2010;110:754–760.[18]*

Additional recommendations from the Society for Pediatric Anesthesia for the use of perioperative opioids in children include regular assessment of level of sedation using a validated sedation score that evaluates the patient's level of alertness as opposed to a scale designed to monitor procedural sedation. The Pasero opioid sedation scale is one such option.[19] Admission to a highly monitored environment, such as a step-down unit, PACU, or ICU, is advised when initiating opioid analgesia in infants younger than three months of age. It is also recommended that continuous monitoring of respiratory rate and electrocardiogram be considered in pediatric patients on oxygen therapy, as supplemental oxygen may impair the sensitivity and response time of pulse oximetry as a monitor for apnea/hypopnea.[4]

PEDIATRIC RESPIRATORY MONITORING AND ASSOCIATED CHALLENGES

As with adults, respiratory monitoring in children should preemptively identify OIRD in time to intervene and prevent the occurrence of critical events. Ideally, respiratory monitoring should continuously and accurately measure oxygenation, respiratory rate, carbon dioxide (CO_2) tension, and airflow.

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Desaturation Can Be a Late Warning Sign of Respiratory Insufficiency When Patients Are Receiving Oxygen

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Monitors currently exist to track each parameter; however, each has limitations as a predictor of impending respiratory failure (Table 1).

The most common monitoring methods in pediatric practice are continuous pulse oximetry and transthoracic impedance plethysmography. Since its introduction to pediatric practice in the 1980s, pulse oximetry has provided critical information regarding adequacy of oxygenation in infants and children. Pulse oximetry monitoring is frequently available on pediatric units, and monitoring itself is well tolerated by patients of all ages. However, desaturation can be a late warning sign of respiratory insufficiency, particularly when patients are receiving supplemental oxygen.[4] Unfortunately, whether due to surgical complexity, patient comorbidities, or analgesic administration, studies report a frequent need for supplemental oxygen to maintain adequate oxygenation postoperatively.[11,18] This need puts children at increased risk of unrecognized hypoventilation by increasing the time between apnea/hypopnea and desaturation.

Transthoracic impedance plethysmography monitoring of respiratory rate, a technique that can identify apnea and hypopnea, hallmarks of opioid effects on brainstem respiratory centers, is also commonly available and well tolerated. However, care must be taken to utilize age-appropriate respiratory parameters. Unfortunately, respiratory rate monitoring using this technique may be inaccurate due to suboptimal ECG electrode placement, motion artifact, and physiological events that cause chest wall movement, such as coughing and crying. Further, it may fail to identify respiratory insufficiency in the setting of undiagnosed airway obstruction.

Measurement of arterial $PaCO_2$ provides a well-validated assessment of ventilation but requires arterial access and does not provide continuous information. Noninvasive surrogate measures of $PaCO_2$ that do provide continuous data include transcutaneous and end-tidal PCO_2 ($etCO_2$) monitoring. Transcutaneous gas monitoring fell out of favor in the 1980s in part due to technical challenges, including the risk of skin burns when used on neonates. However, as a result of technological advances, transcutaneous PCO_2 monitoring is now clinically feasible and safe. These monitors have been evaluated in pediatric populations,[20] but have not been studied in infants and children receiving opioid medications in the postoperative setting. While correlation is good with steady state $PaCO_2$, response time precludes rapid identification of acute changes in ventilation, limiting its utility as an early warning monitor.

Alternatively, End tidal CO_2 ($etCO_2$) monitoring provides early, reliable warnings of ventilatory insufficiency when used to monitor intubated, anesthetized, or deeply sedated patients. Capnography with nasal and oral sampling has been studied in non-intubated adults receiving PCA[2,7] and is a more sensitive indicator of respiratory compromise than saturation monitoring, supporting capnography's potential use as an early warning monitor of impending respiratory insufficiency. In light of these findings, the APSF has recommended that capnography be used to monitor ventilation when supplemental oxygen is provided to postoperative patients receiving opioids. However, appropriate use requires patient cooperation in wearing the specially designed capnography cannula for prolonged periods in order to detect low tidal volumes exhaled from both the mouth and the nose. These cannulas may be uncomfortable or interfere with activities such as eating or talking, impacting patient compliance. And when studied in nonintubated, nonsedated postoperative pediatric patients, capnography was, in fact, often poorly tolerated for these very reasons, limiting implementation in pediatric monitoring paradigms.[21]

A clear understanding of the information provided by capnography monitoring is essential. While capnography provides an accurate measure of respiratory rate, the meaning of $etCO_2$ values may differ substantially between patients with a natural or artificial airway. As noted in the PRODIGY trial, over 60% of patients monitored had episodes of $etCO_2 < 15$ mm Hg (>50% had low $etCO_2$ and low respiratory rate), but no patient had an $etCO_2 > 60$ mm Hg.[7] These results suggest that in many instances $etCO_2$ values did not reflect $PaCO_2$, but were instead a surrogate indicator of poor airflow due to unrecognized obstruction.

Newer technologies, such as noninvasive respiratory volume monitoring, may provide a more sensitive assessment of airflow, specifically tidal volume and minute ventilation. Monitors have been validated in both adults and intubated, mechanically ventilated infants and children under general anesthesia.[6,22] However, in spontaneously breathing adults, tidal volume and respiratory rate trending were good, but accuracy of minute ventilation measurements was limited compared with the gold standard, spirometry.[23] Nevertheless, the trend monitoring that these devices can provide may

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Table 1: Summary of Respiratory Monitoring Modalities for Detection of OIRD.[2,4,6,7,20-23]

Monitor	Parameters measured	Advantages	Disadvantages
Pulse Oximeter	• Oxygen saturation	• High availability • Well-tolerated • Critical threshold values clearly defined	• Potentially late indicator of hypopnea/apnea • Delayed response time when supplemental oxygen provided
Transthoracic Impedance Plethysmography	• Respiratory rate	• High availability • Well-tolerated • Age-appropriate critical threshold values clearly defined	• Hypoventilation due to airway obstruction can be missed • Motion artifacts with movement
Capnography	• Respiratory rate • $etCO_2$	• Good indicator of respiratory rate • Approximate indicator of $PaCO_2$ in intubated patients	• Limited availability outside of operating room and ICU • Poorly tolerated by children • Inconsistent correlation between $PaCO_2$ and $etCO_2$ in patients with natural airway
Transcutaneous CO_2 Monitor	• Skin surface partial pressure of CO_2	• Good correlation with $PaCO_2$ • Critical threshold values clearly defined	• Limited availability • Lacks breath-to-breath monitoring capability • Slow response time precludes identification of acute changes in ventilation • Requires recalibration after 12 hours or if sensor dislodged
Noninvasive Respiratory Volume Monitor	• Respiratory rate • Tidal volume • Minute ventilation	• Good trending of tidal volume and respiratory rate • Well-tolerated	• Rare availability • Limited accuracy of minute ventilation measurements in spontaneously breathing patients • Critical minute ventilation/tidal volume threshold values not defined in children

$etc0_2$=end-tidal carbon dioxide; $PaCO_2$=partial pressure of carbon dioxide; ICU=intensive care unit, CO_2=carbon dioxide.

Capnography Should Be Used When Postoperative Patients Receiving Opioids Are on Supplemental Oxygen

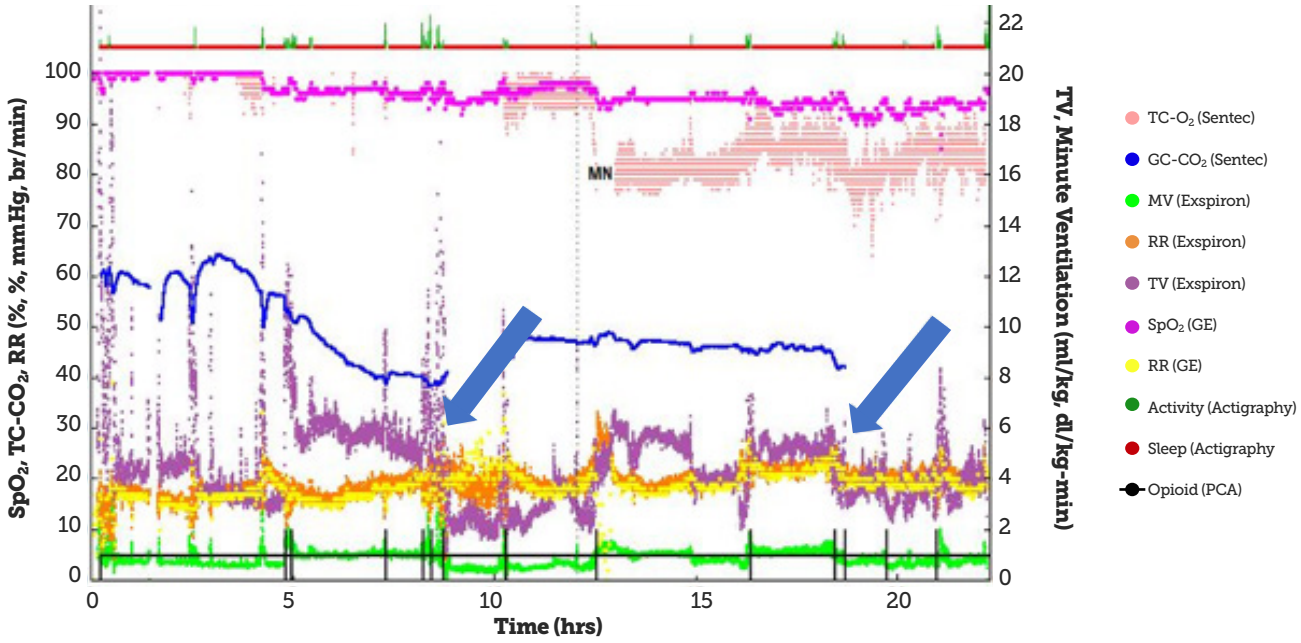

Figure 3: 24-hour data stream of oxygen saturation, respiratory rate, transcutaneous CO_2, minute ventilation, tidal volume, actigraphy and PCA opioid use in adolescent patient following posterior spinal fusion. Decreased tidal volume (TV) after PCA bolus use is demonstrated with blue arrows. MN denotes midnight. (Unpublished data from Constance Monitto).

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support their incorporation in future monitoring strategies. Preliminary data from a pilot study in adolescents receiving PCA opioid following posterior spinal fusion surgery (Figure 3) suggests the monitors are tolerated in adolescents (C. Monitto personal communication), implying that their use in pediatric monitoring paradigms is feasible. That said, critical ventilatory threshold values that could be used to predict impending, or detect present but unrecognized, respiratory compromise have yet to be clearly defined in children.

In conclusion, no models designed to predict the risk of opioid-induced respiratory decompensation in children currently exist. When stratifying risk, patient-specific factors unique to children should be included as opposed to extrapolating results from adult studies. Continuous electronic respiratory monitoring of children is reported to be more commonly utilized than in the care of adults, but no single technology provides a comprehensive solution for monitoring those with a natural airway. In the future, the use of multiple, complementary monitors in conjunction with paradigms designed to include pediatric-specific threshold alarm parameters may allow for earlier identification of episodes of respiratory insufficiency in this vulnerable population.

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The authors have no conflicts of interest.

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RAPID Response
to questions from readers

Pulse Oximetric Pulse Rate: What Are We Measuring?

by Michael Vandenheuvel, MD; Patrick Wouters, MD, PhD; and Luc De Baerdemaeker, MD, PhD

DEAR RAPID RESPONSE:

Since the 1970s, the pulse oximeter (PO) has enabled noninvasive continuous assessment of arterial blood oxygenation as well as pulse rate. The pulse estimate is derived from the plethysmographic waveform and serves as a proxy for pulsatile perfusion. The audible tone supports rate and rhythm monitoring while the bedside clinician is multitasking, with a variable pitch to reflect oxygen saturation. Pulse oximetry based pulse rate monitoring offers an additional source of information since interference can cause ECG-based rate monitoring to be unreliable. The overall utility of PO monitoring is unquestioned, but the underlying technology is complex. Based upon the differential absorption characteristics of oxy- and deoxyhemoglobin and arterial pulsations, there are many factors that can interfere with the PO measurement, and extensive signal processing is required to obtain useful information. This report highlights clinical scenarios where the PO rate measurement and associated tone rate did not adequately change despite significantly altered arterial pulsations.

The observations reported here occurred after a major update of bedside patient monitors in our center. The first observation occurred in patients on cardiopulmonary bypass (CPB), and the second was in non-CPB patients with life threatening arrhythmias. Our monitoring setup consists of a Masimo SET pulse oximeter (integrated SpO_2 version MS:DSP:V05:03.01.08), set to 2–4- or 4–6-seconds data averaging with optical probe RD SET sensors, applied to a digit (or ear, in our asystole case) as per the manufacturer's recommendation (Masimo Corporation, Irvine, California, USA). The PO is integrated into Mindray N1 monitoring, with the PO pulse rate set as the primary source of audible rate representation (Mindray Global, Nanshan, Shenzhen, P.R. China). The *Smart Tone* feature of the Masimo PO is enabled and cannot be disabled. This feature is designed to maintain a variable pitch saturation tone during low signal-to-noise conditions. However, in the CPB setting, false pulse rates are indicated by the PO in at least half of our patients during bypass, even during aortic cross-clamping. The reported rate was not linked to the CPB's pump settings. Figure 1 shows two examples during a period of absent pulsatility where the PO reported a pulse rate close to the previous baseline in the mid-60s. The monitor's audible tone kept a regular pace and stable pitch. We reported this experience to the manufacturer and an initial audit by the company did not identify any malfunctions. The manufacturer's manual stated that *"Masimo SET will continue to report accurate arterial oxygen saturation and pulse rate readings during motion and low perfusion, even when the plethysmographic waveform is suboptimal,"* and that *"It is important to note that even with 'Low Signal IQ,' the measurement has a high probability of being correct; otherwise the system would not display values at all."*[1] In this CPB setting, however, we would suggest that the algorithm fails to correctly reflect the current pulse rate.

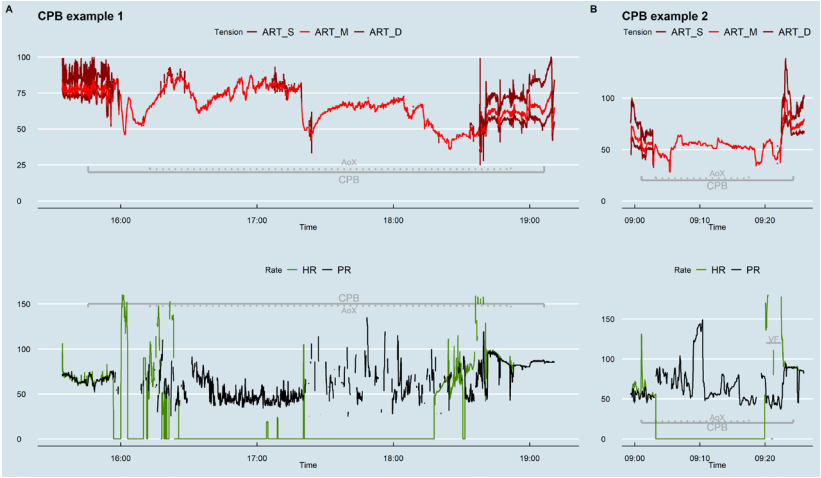

Figure 1: Arterial pressures, ECG-derived heart rate (HR), and pulse oximeter-derived pulse rate (PR) in two cases, during cardiopulmonary bypass (CPB) and aortic cross-clamping (AoX). Note that PR detection is also maintained during ventricular fibrillation (VF) after declamping in the second example.

The second observation involved patients with life-threatening arrhythmias where the Masimo PO pulse rate falsely indicated a stable heart rate and rhythm. We noticed this in one patient who suddenly developed ventricular fibrillation (VF) after CPB was terminated and in two patients with extreme bradycardia. The VF occurred after CPB for aortic valve replacement, during surgical hemostasis, with the sternum still open (figure 2, left panel). The resulting low cardiac output was evidenced by hypotension and a drop in end-tidal carbon dioxide. After 23 seconds, successful defibrillation restored hemodynamics.

Shortly after the VF began, erratic oscillations were captured by the PO sensor that did not exist before or after the VF and subsequent defibrillation, although the patient was lying still, and no major external movement was applied to the patient's finger or PO. During this episode, the PO pulse rate exhibited only a moderate decline in pulse rate 15 seconds after the VF began, falling to 64 beats per minute after 24 seconds. Once again, the Mindray monitor's audible tone reflected this moderate decline in pulse rate. Following the defibrillation, the waveforms of the ECG, arterial pressure, and plethysmographic waveforms show that the heart rate returned to its pre-VF rate; however, the ECG-based heart rate was double counting while the PO pulse rate accurately returned to the pre-VF rate.

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In an asystole case (figure 2, right panel), similar observations are made. This occurred pre CPB, during jugular vein wire instrumentation for ECMO cannula placement. The PO plethysmographic waveform shows an erratic oscillating signal shortly after the asystole began. Despite the sudden asystole with hemodynamic collapse, nadir PO pulse rate reached 67 beats per minute. While the pitch dropped according to the decline in saturation, the ongoing audible rate was not in accordance with the asystole event.

DISCUSSION

The impact of patient movement and low perfusion states on the reliability of *saturation* readings is well known and is being addressed.[2,3] The reliability of PO *pulse rate* measurement, however, remains under-investigated, especially during low or absent pulsatility states and when the audible tone is unaffected. Most comparisons between PO and ECG heart rate have taken place in the neonatal care setting, where pulse oximetry is known to underestimate heart rate in the first minutes after birth.[4] Studies report up to 35% false bradycardia readings,[5] and an overall sensitivity of (only) 89% for detecting a heart rate below 100 beats per minute.[6]

We reported our observations and concern for clinical consequences to both Masimo and Mindray corporations. Of note, similar observations were previously reported to Masimo in 2007,[7] upon which Masimo adjusted their software allowing a disabling of the *Smart Tone* setting. *Smart Tone* was originally developed to minimize the impact of motion artifacts, but here we confirm that this algorithm may be misled by severe rhythm disturbances as well. In our current Mindray monitors, however, the *Smart Tone* feature is permanently enabled. This is probably the cause for the misleading audible tone rate, and the manufacturers are addressing this issue so that it can be suppressed in the Mindray monitor. In the meanwhile, we are extra vigilant and adjust the pulse rate measurement source to the arterial line whenever possible. In this setup, the pulse pitch is still derived from the PO signal, but the audible pulse rate is a reflection of the actual pulse rate.

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The authors have no conflict of interest.

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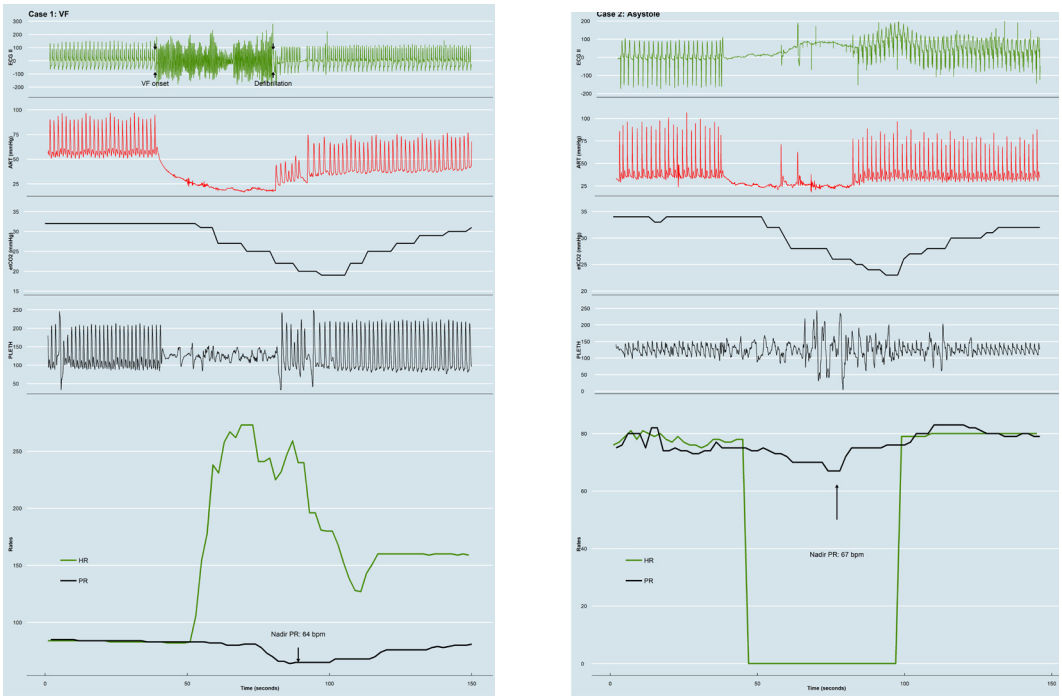

Figure 2: ECG, arterial pressure, end-tidal capnography, and pulse oximetry data, as well as ECG-derived heart rate (HR) and pulse oximeter-derived pulse rate (PR). Sudden onset ventricular fibrillation (left) and acute asystole (right) with hemodynamic effects, without significant effect on pulse oximetric pulse rate measurement.

RAPID Response
to questions from readers

Pulse Oximeter: Response

Pulse Rate from Pulse Oximeter Displayed and Audible Tone Generated During Absence of Physiologic Pulse—*Masimo Response*

IN REPLY:

Masimo carefully reviewed the report by Vandenheuvel et al., and identified important insights to share with the readers. In addition to submitting the report to APSF, UZ Ghent contacted Masimo to report cases where the pulse rate (PR) measurement and associated variable pitch tone from the Masimo SET board in a Mindray monitor did not indicate the actual pulse rate during cardiopulmonary bypass (CPB) and in the two non-CPB cases involving pulseless arrhythmias (ventricular fibrillation [VF] and asystole). Masimo was provided the pulse oximeter (PO) sensor used in the asystole case (RD SET E1 Ear Sensor), a digital dataset from the Mindray monitor, and alarm messages (plotted in Figure 3, top panel). Limited Mindray datasets (but not the sensors) were available for the VF and CPB cases. The compressed physiological waveforms shown in the report to APSF were also forwarded to Masimo.

Masimo tested the ear sensor, which operated within specifications. The parameter and alarm data for the asystole case were compared with compressed waveforms provided for ECG, arterial pressure, $EtCO_2$, SpO_2 plethysmography waveform (pleth), and trend plots for ECG-based heart rate (HR) and plethysmography-based PR.

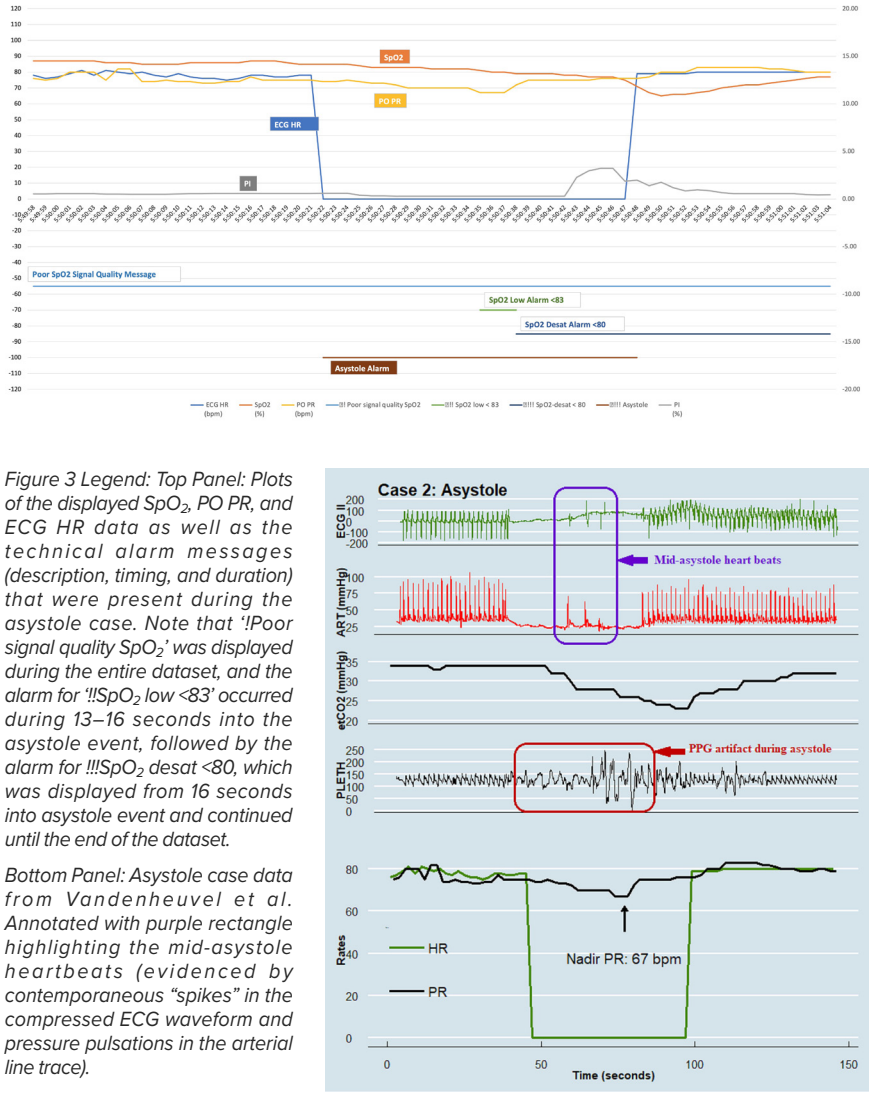

Figure 3 Legend: Top Panel: Plots of the displayed SpO_2, PO PR, and ECG HR data as well as the technical alarm messages (description, timing, and duration) that were present during the asystole case. Note that '!Poor signal quality SpO_2' was displayed during the entire dataset, and the alarm for '!!SpO_2 low <83' occurred during 13–16 seconds into the asystole event, followed by the alarm for !!!SpO_2 desat <80, which was displayed from 16 seconds into asystole event and continued until the end of the dataset.

Bottom Panel: Asystole case data from Vandenheuvel et al. Annotated with purple rectangle highlighting the mid-asystole heartbeats (evidenced by contemporaneous "spikes" in the compressed ECG waveform and pressure pulsations in the arterial line trace).

KEY FINDINGS:

- Per the UZ Ghent team, asystole started pre-CPB, during attempt to insert an ECMO wire/cannula into the jugular vein and ended 26 seconds after efforts ceased.
- The compressed waveforms show a few pulsatile beats during the asystole event on the ECG, arterial, and plethysmography waveforms.
- The Mindray monitor (with Masimo SET) messaged low SpO_2 signal quality long before and after the event. This is important because low signal quality can impair timely, accurate measurements.
- The plethysmography waveform recorded an oscillating signal shortly after the asystole began. Given the PO sensor's ear attachment, it is quite possible the physician actions, in proximity to head/neck/ear, during insertion and removal of the ECMO wire/cannula caused unintended motion and the resulting artifact seen in the plethysmography waveform that influenced the PO-based PR measurements. Masimo SET is designed to trigger an alarm in <8 seconds of an asystole in the absence of motion artifact. Timely recognition of the asystole event by the PO was likely impeded by the oscillatory artifact in the plethysmography signal and mid-asystole heartbeats visible in both the ECG and arterial waveforms (see purple box in Figure 3), impacting the accuracy of the PR estimate.
- The Mindray data show an SpO_2 decline from 85% to 67%, and a low SpO_2 alarm occurred ~13 seconds after the asystole began.

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Pulse Oximeter: Response, Cont'd

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UZ Ghent did not provide Masimo with the sensor used in the VF case. However, they did send compressed parameter waveforms and 1 Hz parameter data, but no alarm message data. Key findings from the review of this data include:

- Ventricular fibrillation lasted ~24 seconds ending with defibrillation.
- The compressed waveforms show no visible artifact until a few seconds after the VF onset when an erratic oscillating signal appears on the plethysmography.
- The erratic plethysmography signal likely reflects motion artifact caused by clinicians during preparation and delivery of defibrillation, as this artifact was not present before or after the VF episode.

It is well recognized that different physiological monitoring parameters have unique accuracy, stability, reliability and confounder characteristics. For example, the HR post-defibrillation in the VF case highlights a signal-based limitation of ECG monitoring. The ECG tracing shows the HR return to its pre-VF rate of 78–80 BPM. However, presumably pronounced "T" or "P" waves in the post-defibrillation ECG caused the HR to double-count, while the PO-generated PR accurately returned to the pre-VF rate.

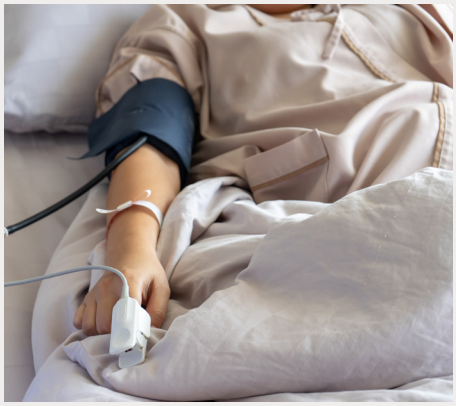
Similarly, the plethysmography waveform, which measures optical density changes in the sensor's path, has limitations based on the origin of the signal. Specifically, in the absence of a true arterial pressure pulse, a confounding oscillatory signal that may mimic the shape of a true plethysmography (either clinician/motion or apparatus induced), can present a PR that is not representative of the ECG-derived HR.

It is important to note that Masimo's plethysmography waveform reflects the raw signal recorded by its optical sensor; therefore, the waveform shape is representative of a true change in optical signal. Masimo SET's unique signal processing algorithms are designed to accurately estimate pulse rate and oxyhemoglobin saturation during motion and low perfusion; however, the scenario in the asystole case, where there is no true arterial pressure pulse, but an oscillating plethysmography signal due to confounding factors, presents a limitation of pulse oximetry technology in general.

In the CPB examples, both cases show wide variability of mean arterial pressure during CPB. In the first case, both the ECG-derived HR and PO-derived PR are elevated when the heart is not pumping. The nonphysiologic plethysmographic waveform is likely due to a small pulse pressure produced by the CPB roller pump, a phenomenon long known by cardiac anesthesia professionals.[1] Masimo SET is often capable of detecting these pulsations,[1] but PO is not reliable during CPB. Indeed, Reich et al. reported that CPB accounted for over 30% of cases when PO data were unreliable for at least 10 minutes.[2]

Lastly, in Vandenheuvel et al's discussion, the authors mistakenly say that Masimo's *"Smart Tone was originally developed to minimize the impact of motion artifacts."* Masimo's SmartTone feature solely determines whether the variable pitch tone is enabled during low signal-to-noise conditions. If SmartTone is enabled, a tone reflecting the frequency of the PR and the pitch reflecting the SpO_2% will be enunciated. If SmartTone is disabled, no pulse tone will be enunciated during low signal-to-noise conditions. The ability to hear the variable saturation pitch and PR frequency during low signal conditions is often well received in care areas where artifact is common and patients are consistently observed, and is less suitable in care areas where these conditions are not common.

The SmartTone feature is a configurable setting in Masimo monitors and defaulted to OFF to minimize the likelihood of SmartTone being enabled without a user understanding how it works and knowing how to turn SmartTone ON or OFF based upon the circumstances in their use case. However, in the current deployment on Mindray monitors, SmartTone is defaulted "ON" and cannot be turned "OFF." Pursuant to learning about the experiences at UZ Ghent, Mindray considered the clinical and technical issues with an open mind, and they have agreed to make SmartTone a configurable setting defaulted to "OFF."



In summary, the cases highlighted by the physicians from UZ Ghent provide insights and warnings for clinicians about confounding conditions that can affect PO-based PR and ECG-based HR measurements, as well as the potential downside in some clinical applications of a unique deployment of the SmartTone feature in a multiparameter monitor. Masimo and Mindray utilize feedback from our customers as vital inputs for potential opportunities to enhance user satisfaction of our products, as shown by the planned change in SmartTone deployment in Mindray monitors resulting from the collaboration with UZ Ghent physicians.

Sincerely,

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Disclosures: Vikrant Sharma, Rick Fishel, Daniel Cantillon, and William C. Wilson, are full-time employees of Masimo. Steven J. Barker is a part-time Masimo employee.

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Society of Anesthesia and Sleep Medicine: Safety of Patients with Obstructive Sleep Apnea in the Perioperative Period

by Mandeep Singh, MBBS, MD, MSc, FRCPC; Jennifer E. Dominguez, MD, MHS; Melanie Lyons, PhD, ACNP; Satya Krishna Ramachandran, MD, MBA; and Bhargavi Gali, MD, MHA

INTRODUCTION

The Society of Anesthesia and Sleep Medicine (SASM) was founded in 2010 as a collaboration between anesthesia professionals and sleep specialists focused on the perioperative safety of patients with sleep disorders. Obstructive sleep apnea (OSA) is one of the sleep disorders that has become recognized as a risk factor for perioperative complications.[1,2] SASM has been involved in research and education in the management of patients with OSA and at high risk of undiagnosed OSA in the perioperative period, including development of guidelines to address provision of safe care.[3-5] Other sleep disturbances can impact provision of optimal care in the perioperative period, and SASM continues to work to identify and address knowledge gaps of providers to help optimize patient outcomes.[3-7]

SASM continues to work to identify ongoing needs for education and further research, in addition to utilizing the expertise of sleep specialists and anesthesia professionals to provide guidance in preventing and detecting adverse events in the perioperative period (Figure 1).

POSTOPERATIVE MANAGEMENT, AND CLINICAL GUIDELINES

Obstructive sleep apnea (OSA), a prevalent sleep-related breathing disorder in perioperative environments, is characterized by repeated upper airway collapses that may lead to reduced oxygen saturation during sleep and a heightened risk of chronic cardiovascular diseases.[8] The surgical population exhibits a higher frequency of OSA compared to the general population.[9] In a retrospective nested cohort study, 819 surgical patients underwent either laboratory or portable polysomnography (PSG). Clinical diagnosis of OSA was determined through chart reviews conducted by surgeons and anesthesia professionals who were blinded to the PSG results. Among the 267 patients identified with moderate-to-severe OSA prior to surgery, 92% (n=245) had not been diagnosed by surgeons, and 60% (n=159) remained undiagnosed by anesthesia professionals.[10] This condition is linked to increased perioperative complications[2] and consequently, increased hospital and resource utilization.[11-14]

Although guidelines for preoperative screening[3] and intraoperative management[4] of OSA patients have been disseminated, a gap persists in evidence-based directives for postoperative care. The development of an evidence-based system for triaging patients with confirmed or suspected OSA is critical when they are admitted post-surgery to ensure the judicious allocation of resources for the management and enhancement of OSA. Moreover, the post-discharge counseling for patients lacks clarity, necessitating evidence-based guidelines established in partnership with patient advocates. Such guidelines are crucial for those undergoing ambulatory surgery, who return home on the same day of the operation, often while under opioid analgesia. Moreover, a significant portion of inpatients, who are initially under close observation in the Post Anesthesia Care Unit (PACU) and Intensive Care Unit (ICU), are later transferred to general care floors where monitoring might not be sufficient for the early detection of vital ventilatory changes.[15]

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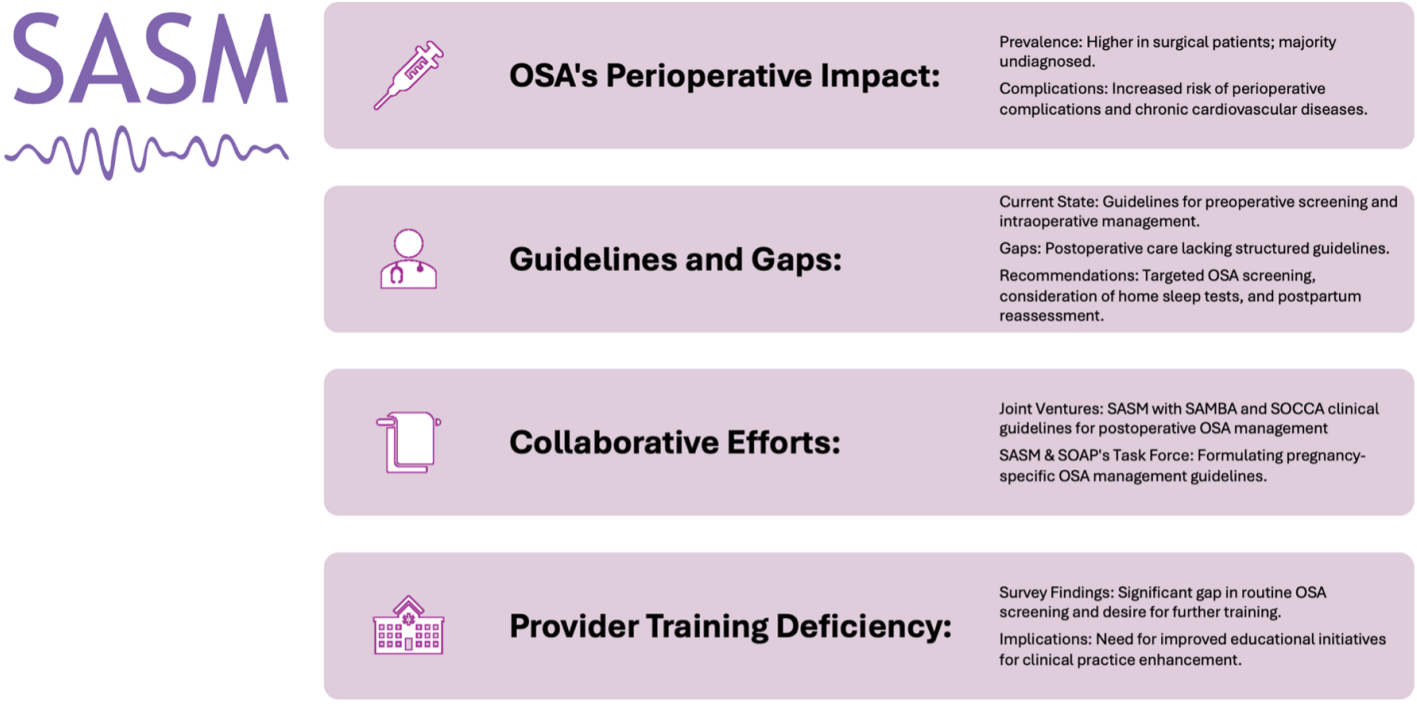

Figure 1: Heeding the "Don't Look Up'" Call—Society of Anesthesia and Sleep Medicine Leadership, and Collaborative approach to Perioperative Sleep Health Research, and Innovation.

SAMBA: Society for Ambulatory Anesthesia; SASM: Society of Anesthesia and Sleep Medicine; SOAP: Society for Obstetric Anesthesia and Perinatology; SOCCA: Society of Critical Care Anesthesiologists.

SASM Creating Guidelines of Postoperative Management For OSA Patients

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To bridge these knowledge gaps, the Society of Anesthesia and Sleep Medicine (SASM) has embarked on a joint venture with the Society for Ambulatory Anesthesia (SAMBA) and the Society of Critical Care Anesthesiologists (SOCCA), aiming to establish evidence-based guidelines for the postoperative management of OSA patients. This initiative aims to augment the SASM's evidence-informed recommendations for preoperative[3] and intraoperative[4] management of OSA, along with the SAMBA's consensus for the ambulatory management of such patients.[16] The collaborative guidelines task force is working on recommendations for risk stratification and identification of OSA, postoperative analgesia regimen, postoperative OSA treatment options, monitoring standards, and postoperative discharge considerations, including patient counseling.

In alignment with our mission to foster collaborative, evidence-based perioperative care, SASM offers expert opinion-based recommendations for managing patients with OSA that provide a continuum of strategies from preoperative screening to postoperative follow-up[17] (Table 1).

Table 1: Perioperative Management Strategies for Patients with Obstructive Sleep Apnea.[17]

Perioperative Phase	Recommendations and Considerations
Preoperative Screening	• Implement routine OSA screening using validated screening tools like the STOP-Bang, or other questionaires. • For diagnosed OSA, particularly in patients with comorbid conditions, review results from PSG (for nature, and severity of OSA), or CPAP downloads (for treatment compliance), whenever possible. • For parturient: Screen pregnant people with BMI > or equal to 30 kg/m^2, hypertensive disorders of pregnancy and/or gestational diabetes in the first or second trimester; recommend using screening tools validated in pregnant populations.
Intraoperative Management	• Whenever possible, prioritize local or regional anesthesia. • Use continuous capnography for patients undergoing moderate to deep sedation. • Consider definitive airway for patients undergoing general anesthesia, as there is a higher propensity for upper airway closure and oxygen desaturations if deep planes of anesthesia are desirable for the surgical procedure. • Ensure careful airway management and consider nonsupine positions for extubation. • Ensure complete reversal of sedative, and neuromuscular blockade following general anesthesia. • Plan for the availability of CPAP and adopt an opioid-sparing, multimodal approach to analgesia.
Postoperative and PACU	• Semi-upright position for recovery. It has been shown that semi-upright position can decrease the AHI, upper airway collapsibility and hence be protective in patients with OSA. • Monitor patients for desaturation, hypopnea, apnea, or other respiratory events, pain-sedation mismatch in the PACU. Persistent events may necessitate higher levels of monitory postoperatively. • For patients with new initiation of PAP or notable PACU events, consider postoperative care in a step-down unit or ICU. • Minimize the use of long-acting opioids, titrating to the lowest effective dose. • Verify functionality of the patient's PAP equipment if brought from home.
Management of Respiratory Depression	• Initiate appropriate interventions, including noninvasive ventilation or opioid antagonists, if needed. • Monitor hospitalized patients in units with experience in OSA, considering enhanced monitoring, if available.
Ambulatory Surgery	• Select patients with optimized comorbidities for ambulatory surgery, employing regional
Home Treatment and Follow-Up	• Advise consistent use of PAP therapy and limited opioid use post-discharge. • Arrange for follow-up care with appropriate providers for patients with suspected OSA.

OSA: Obstructive Sleep Apnea, CPAP = Continuous Positive Airway Pressure, ICU: Intensive Care Unit, , PACU = Post-Anesthesia Care Unit, PAP = Positive Airway Pressure, PSG = Polysomnography.

PROVIDER KNOWLEDGE ON OSA MANAGEMENT

Assessing the awareness and practices concerning OSA among health care professionals, SASM, with the support of the American Academy of Sleep Medicine Foundation (AASM), led a multisite survey. This extensive study canvassed nine prominent academic institutions and spanned physicians in training and Advanced Practice Providers (APPs) in the fields of Anesthesiology, Internal Medicine, Family Medicine, Surgery, and Obstetrics and Gynecology (OB/GYN), bringing invaluable insights into OSA's perioperative management.[18] Both physicians-in-training and APPs reported that they did not feel their training regarding OSA was adequate. Only 51% overall with 82% in Anesthesia, 34% in Surgery, and 12% in OB/GYN reported they felt adequately trained. Across all specialties, 77% desired additional training. When asked about training to assess for OSA in the perioperative period, only 38% of all participants reported feeling that they had been adequately trained. This included 84% in Anesthesia, 33% in Surgery and 15% in OB/Gyn. This opportunity to improve clinical practice was reflected in the participants' perception of their training .

CLINICAL GUIDELINES FOR MANAGEMENT OF OBSTETRIC PATIENTS WITH OSA

Recent studies have highlighted the maternal morbidity associated with OSA; it has been particularly associated with hypertensive disorders of pregnancy and gestational diabetes mellitus.[19-23] The correlation of maternal OSA with neonatal outcomes such as pre-term birth, Apgar scores, and low birth weight, however, remains contentious.[24-27] Pregnancy is a dynamic state during which physiologic changes and weight gain, along with pathophysiologic changes related to conditions such as preeclampsia present unique challenges for clinicians in the screening, diagnosis, and management of OSA that had not been addressed in the available literature. Thus, SASM and the

See "SASM," Next Page

Maternal Morbidity is Associated with OSA

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Society for Obstetric Anesthesia and Perinatology (SOAP) assembled a task force of experts to review the available evidence and generate recommendations on the screening, diagnosis, and treatment of patients with OSA during pregnancy including expert opinion where evidence was lacking. The multidisciplinary committee was composed of anesthesia professionals, sleep medicine specialists and research scientists, maternal fetal medicine specialists, and a research librarian. These recommendations were published in *Obstetrics and Gynecology* in August 2023 (https://journals.lww.com/greenjournal/abstract/2023/08000/society_of_anesthesia_and_sleep_medicine_and_the.22.aspx).[28]

The guidelines do not recommend screening all pregnant people for OSA, but do suggest screening those people with pre-existing risk factors for OSA including BMI > 30 kg/m^2; hypertensive disorders of pregnancy; and/or gestational diabetes in the index or prior pregnancy. The recommended timing of screening is between 6–29 weeks' gestation. The Guideline committee reviewed several OSA screening tools that had been studied in pregnant populations and suggest that screening tools that have been validated in pregnant cohorts are the most promising for predicting OSA in this population. Recommendations regarding the diagnosis of OSA in parturients focus on considering home sleep tests when appropriate, as well as considering repeat postpartum testing due to the dynamic airway changes that occur during and after pregnancy. Treatment guidance emphasizes the lack of evidence that OSA treatment modulates any pregnancy-specific outcomes, but that OSA treatment is still indicated in pregnancy to treat symptoms, modify objective measures of OSA, and to improve quality of life. These are the first guidelines to address specific considerations for OSA management in those that are pregnant.

CONCLUSION

The integration of the SASM's comprehensive approach across the continuum of OSA management—from preoperative assessment to postoperative and long-term care—underscores the necessity of a multifaceted strategy. The article has provided a cohesive narrative that aligns with the Society's overarching goal of improving patient safety and outcomes in anesthesia and sleep medicine.

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Announcing the Availability of *Preventing Surgical Fires* Videos in English, Spanish, and French

Preventing Surgical Fires is a new video from the APSF focused on preventing patient harm from fire. The original APSF video, entitled *Prevention and Management of Operating Room Fires*, remains available and provides guidance on both prevention and management. The new video is shorter and offers practice guidance intended to make patient harm from fire a never event. As shown in the APSF Fire Prevention Algorithm, eliminating enriched oxygen from the area at risk for fire is a fundamental strategy for preventing serious fires. *Prevención de Incendios Quirúrgicos* is the Spanish version of the video, and *Prévention des Incendies Chirurgicaux* is the French version.

The working group responsible for these videos consisted of the following individuals:

Steven J. Barker, MD, PhD, University of Arizona

Karen B. Domino, MD, MPH, University of Washington

Elizabeth M. Elliott, MD, Nemours Children's Health

Jeffrey M. Feldman, MD, University of Pennsylvania

Megha Karkera Kanjia, MD, Baylor College of Medicine

David C. Lyons, MD, University of Rochester

Rafael Ortega, MD, Boston University

Keith J. Ruskin, MD, University of Chicago

George A. Schapiro, MSIA, Anesthesia Patient Safety Foundation

Deborah A. Schwengel, MD, MEd, Johns Hopkins University

Many of this group are well-known in the anesthesia community for their long-term dedication and contributions to patient safety and particularly to surgical fire prevention.

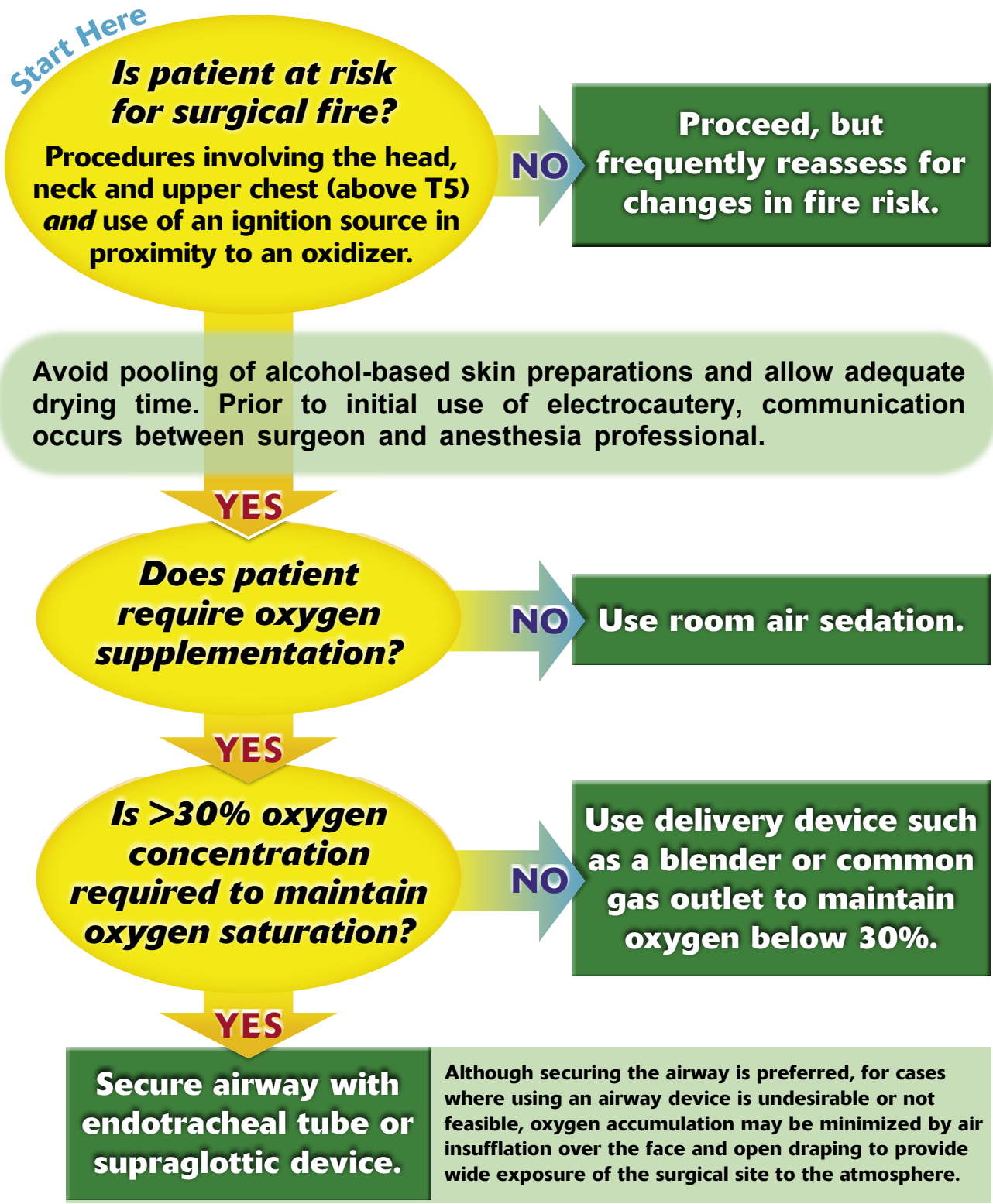
Special thanks go to Rafael Ortega and Jeff Feldman for their extraordinary effort and outstanding contributions in the production of these videos. Thanks also to Dan Cole for the APSF initiative and support for this project.

The videos can be viewed or downloaded at **apsf.org/fire**.

SURGICAL FIRES – A PREVENTABLE PROBLEM

Preventing Surgical Fires (5 min.)

OR Fire Prevention Algorithm



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The following organizations have indicated their support for APSF's efforts to increase awareness of the potential for surgical fires in at-risk patients: American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiologist Assistants, American College of Surgeons, American Society of Anesthesia Technologists and Technicians, American Society of PeriAnesthesia Nurses, Association of periOperative Registered Nurses, ECRI, Food and Drug Administration Safe Use Initiative, National Patient Safety Foundation, The Joint Commission

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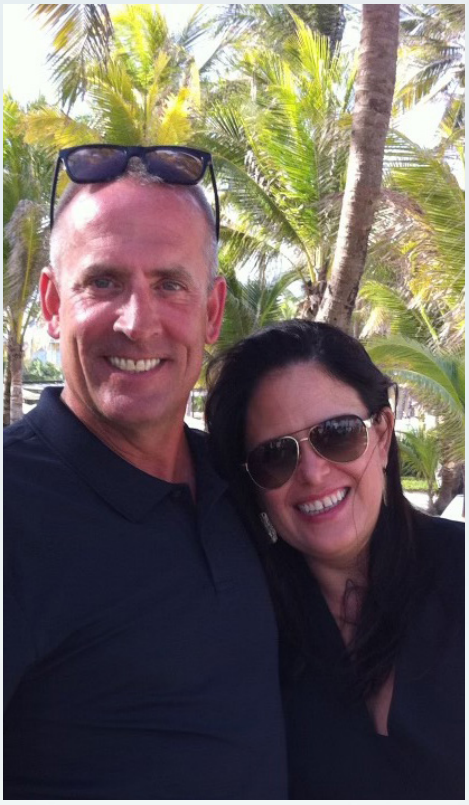
SPOTLIGHT on Legacy Society Members

Dru and Amie Riddle

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

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

Brian Thomas and Keri Voss



As the Vice President of Risk Management for Preferred Physicians Medical (PPM), a leading insurer of anesthesia practices across the country, I've devoted nearly my entire professional career as an attorney to providing risk management services for anesthesia professionals to improve patient safety. PPM has been a corporate sponsor of and patient safety partner with the Anesthesia Patient Safety Foundation (APSF) for over 30 years. During that time period, the APSF and PPM have collaborated on many important patient safety initiatives and projects including, but not limited to, authoring, and co-authoring several patient safety articles in the *APSF Newsletter*, the *ASA Monitor*, and *Anesthesia & Analgesia*. I have also had the pleasure to serve as a guest speaker for the ASPF Stoelting Conference and contributed to the APSF Patient Safety Podcast and the *APSF Newsletter* "In the Literature" synopsis summaries.

My personal experience with the APSF began over a decade ago when one of my mentors and fellow APSF Legacy Society Member, Steve Sanford, introduced me to the APSF family and my first Stoelting Conference. Since then, I have had to the privilege and honor to serve on the *APSF Newsletter* Editorial Board and Corporate Advisory Council since 2018 and the APSF Board of Directors since 2019. The APSF is one of the most widely recognized and respected patient safety organizations in the world. Being part of such a noble organization and working alongside some of the most brilliant, tireless, and diverse anesthesia leaders and stakeholders, as we continue to strive to fulfill the APSF Vision "that no one shall be harmed by anesthesia care," has been one of the most rewarding experiences of my professional career. It is for these, and many more, reasons that my wife, Keri, and I are proud to be able to join the other generous members of the APSF Legacy Society in supporting the APSF into the future as part of our estate plan.

An abiding belief in safeguarding the future of anesthesiology.

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

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

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

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Preoperative Transfusion and Sickle Cell Disease in the Pediatric Patient

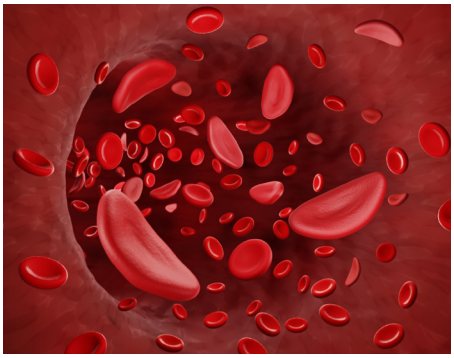
by Rahul Baijal, MD; Priti Dalal, MD; and Megha Kanjia, MD

There is an ongoing focus on delivery of safe and high-quality care to patients in anesthesiology. Patient optimization prior to receiving an anesthetic is crucial to ensuring optimal patient care. The optimization of the pediatric patient with sickle cell disease (SCD) has been an area of continued interest, given its incidence and the perioperative implications of the disease. Children with SCD have a different perioperative risk profile from adults because of the cumulative effect of sickled RBCs on end-organ dysfunction.

SCD is a common hematologic defect with a substitution of valine for glutamic acid on the beta chain of hemoglobin, occurring in about 1 out of 365 African American births. In the United States, approximately 70,000 to 100,000 persons have SCD, with 2.6% of individuals of Mediterranean, Asian, and African origin affected.[1] Patients may be either homozygous (HbSS), heterozygous (HbSC), or have an associated thalassemia (Hb-S-beta^0 or Hb-S-beta$^+$). The most severe clinical manifestations occur in patients with HbSS and Hb-S-beta^0. The red blood cells (RBC) in these patients, when deoxygenated, undergo polymerization leading to RBC deformity (i.e., sickling), subsequent hemolysis, and vaso-occlusion.[2] This RBC damage, precipitated by hypoxemia, hypothermia, hypovolemia, infection, pain, stress, and surgery can inhibit blood flow and cause ischemic injury, producing the symptoms of a sickle cell crisis, such as a pain crisis, acute chest syndrome, chronic organ damage, and musculoskeletal complications.

Surgery and general anesthesia pose challenges in maintaining homeostasis to decrease the physiologic triggers that may precipitate a sickle cell crisis. Children with SCD are at an increased risk for the following postoperative complications, with the incidence of an acute chest syndrome (ACS) of 3.08%, stroke of 0.2%, and 30-day mortality of 0.2%.[3] Intravenous hydration, thermoregulation, and adequate oxygenation are part of the perioperative management aimed at preventing sickle cell crises.[4,5] As with many circumstances, the clinical judgement of the perioperative team is imperative in the determination of the risk versus benefit of a preoperative transfusion in a patient with SCD.

The most common pediatric procedures are low-to-moderate risk (e.g. pressure equalizing tube insertion, laparoscopic cholecystectomy, tonsillectomy/adenoidectomy, laparoscopic splenectomy, umbilical hernia repair, laparoscopic appendectomy, and myringotomy tubes) as compared to adults who may undergo more high-risk procedures (e.g., cardiac surgery and cerebral revascularization).[4-10] In addition, limiting unnecessary blood transfusions in children is a significant consideration to avoid alloimmunization, volume overload, and immunosuppression.[11-13] The incidence of alloimmunization in SCD ranges from 7% to 58% depending on age, number of previous transfusions, and use of red cell phenotypic matching. Children with a history of multiple alloantibodies, delayed hemolytic transfusion reaction , and/or hemolysis have an increased risk of adverse outcomes secondary to transfusion; therefore, careful consideration should be given prior to any transfusion.[14,15]



The decision to administer a preoperative blood transfusion is part of the optimization strategy for SCD patients by hematologists and anesthesia professionals to decrease the percentage of sickled RBCs. The hope is to potentially decrease the risk of perioperative complications, especially in high-risk SCD patients; however, the literature around this topic has shown ambiguous results.[5] Even though the American Society of Hematology 2020 guidelines suggest a preoperative transfusion to a hemoglobin level of 9 or 10 g/dL in all patients with SCD undergoing operations requiring general anesthesia lasting more than one hour, there still remains controversy over the appropriate preoperative transfusion strategy given the current evidence.[6]

There are limited studies in children on preoperative transfusions in children with SCD. For example, the Transfusion Alternatives Preoperatively in Sickle Cell Disease trial was a randomized controlled trial comparing the incidence of perioperative complications in patients who did or did not receive a preoperative transfusion. The trial, which included both adults and children, reported a lower incidence of perioperative complications in patients who were transfused preoperatively versus those who were not transfused.[7] The transfusion arm was either 1) a simple transfusion to increase the hemoglobin (Hgb) transfusion to 10 g/dL in those patients with a Hgb less than 9 g/dL or 2) a partial exchange transfusion to decrease the Hgb S (Sickle cell Hemoglobin) percentage to less than 60% in those patients with a Hgb greater than 9 g/dL. Those patients who received a preoperative transfusion had a lower risk of postoperative acute chest syndrome and life-threatening complications ($p = 0.023$). There was no difference in postoperative pain crisis, hospital length of stay, or readmission rates. This study was small (n = 67) and heterogeneous, 40 children and 27 adults, making it difficult to quantify the benefit of preoperative transfusion in children with SCD.

While the above study was aimed at simple versus partial exchange transfusions, another randomized multicenter trial has evaluated outcomes in SCD patients following simple versus exchange transfusion.[5] Participants in this study were randomized preoperatively to receive either an exchange transfusion regimen to decrease the Hgb S level to less than 30%, or a regimen with a simple transfusion to increase the Hb level to 10 g/dL. Cholecystectomy, head and neck surgery, and orthopedic surgery were the most common procedures in the study with children comprising over 90% (n = 502) of the cohort. Transfusion-related complications occurred in 14% of the exchange transfusion arm and 7% in the simple transfusion arm. The incidence of postoperative acute chest syndrome was 10% in both groups.[5] A simple transfusion was as effective as an exchange transfusion at preventing perioperative complications in patients with SCD.

The observations reported by the above studies, however, differed from a study evaluating outcomes data related to SCD and blood transfusions from the American College of Surgeons NSQIP (National Surgical Quality Improvement Program) Pediatric database. In that study, a retrospective cohort of 357 children with SCD, undergoing low to moderate risk surgery (laparoscopic cholecystectomy, splenectomy, or appendectomy), suggested no difference in 30-day readmission rates, surgical site infections, wound dehiscence, pneumonia,

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Controversy Remains Over the Appropriate Preoperative Transfusion Strategy in SCD Patients

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unplanned reintubation, venous thromboembolism, urinary tract infection, postoperative transfusion, cardiac arrest, stroke, sepsis, and death in children who were transfused preoperatively versus those who were not transfused (p = 0.80).[8] The 30-day rate of surgical complications did not differ between the groups (p = 0.84). Further subgroup analysis, defined by either a preoperative hematocrit greater than 27.3% or less than 27.3%, showed no difference in postoperative sickle cell crisis in those children who were transfused versus those who were not transfused. Preoperative transfusion, additionally, was not associated with a reduced rate of postoperative transfusions in this cohort.

Thus, the current evidence supporting routine preoperative transfusion in children with SCD is inconsistent and inconclusive and does not favor routine preoperative blood transfusion. Hence, the decision for a preoperative transfusion should be patient-specific considering the SCD genotype, baseline hemoglobin, disease severity, risk classification of the surgery, and history of prior surgical complications. An interdisciplinary team, consisting of anesthesiology, hematology, and surgery, is important for perioperative management. An initial stepwise preoperative analysis should precede any decision to transfuse preoperatively (Table 1). The decision for transfusion depends on the risk categorization based on the severity of SCD and type of surgery (Table 2).[4-6] A possible recommended plan based on these considerations is shown in Table 3 and Table 4 for low-risk SCD and high-risk SCD, respectively.[7,9]

In summary, the decision to transfuse children with SCD in the perioperative period should be guided by disease severity and the surgery category. Patients who may benefit from transfusion are patients at high risk for decompensation and include those who are either undergoing a high-risk procedure or at baseline have a high-risk disease state. Future research should focus on creating guidelines and protocols to guide clinicians as they strive to ensure safe and quality care in these high-risk patients.

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Table 1: Preoperative Evaluation of the Child with SCD.[16,17]

Documentation of Baseline Pulmonary Status and Risk for Stroke
• Baseline SpO_2 • Known baseline snoring or other obstructive sleep apnea (OSA) manifestations • In patients with Hb SS or Hb S-beta 0, Transcranial Doppler (TCD) results within the preceding 12 months • Consider a preoperative chest X-ray in the setting of new cough or lower respiratory symptoms (i.e., wheezing, rhonchi, crackles) as these findings may warrant a delay of surgery given concerns of ACS
Laboratory Assessment
• Complete blood count (CBC) with reticulocyte count preoperatively (ideally on day of surgery or within 48 hours of the procedure) • For patients requiring Hgb S <30%, obtain hemoglobin profile within 3 days of surgery in order to obtain baseline Hgb S percentage • Screening Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) if concern for liver disease, history of clinically significant bleeding, or undergoing high-risk surgery

Table 2: Risk Stratification Based on Disease Severity and Type of Surgery.[16,17]

Severity of SCD	Risks for Types of Surgeries
Low-risk SCD: • Hgb > 9 g/dl • SaO_2 > 94% • < 2 acute chest events in the past 5 years • No history of stroke in the past 3 years • American Society of Anesthesiologists (ASA) Class I-II • Normal TCD within 12 months for patients with Hb SS or Hb S-beta 0 • No febrile illness or pain event in 2 weeks preceding surgery • Not diagnosed with persistent asthma • Normal serum creatinine and no gross albuminuria if applicable • Not diagnosed with persistent asthma **High-risk SCD:** All patients who do not meet criteria for low risk	**Low Risk:** Magnetic Resonance Imaging, Inguinal hernia repair, Circumcision, Myringotomy tubes, Dental restorations **Moderate Risk:** Tonsillectomy, Cleft palate/cleft lip repair, Laparoscopic procedures, such as a cholecystectomy, splenectomy, or appendectomy, Total hip replacement **High Risk:** Intracavitary procedures (intracranial, intrathoracic, intra-abdominal), Major orthopedic and plastic surgery (scoliosis repair, free flap)

Table 3: Plan for Low-risk SCD.[16,17]

Low-risk disease AND low-risk surgery	• No transfusion needed
Low-risk disease AND moderate-risk surgery	• Consider transfusion if: – Surgery will require general anesthesia for longer than 1 hour and patient's baseline Hgb is ≤ 9 g/dL – Goal of transfusion is Hgb = 10 g/dL, avoid Hgb > 12 g/dL
Low-risk disease AND high-risk surgery	• Transfuse with goal of Hgb S < 30% • Elective surgery, achieved by simple transfusions • Urgent surgery, achieved by exchange blood transfusion

Table 4: Plan for High-risk SCD[16,17]

High-risk disease AND low-risk surgery	Transfusion may not be necessary.
High-risk disease AND moderate-risk surgery	• Consider transfusion if: – Surgery will require general anesthesia for longer than 1 hour and patient's baseline Hgb is ≤ 9 g/dL – Goal of transfusion is Hgb = 10 g/dL, avoid Hgb > 12 g/dL
High-risk disease AND high-risk surgery	• Transfuse with goal of Hgb S < 30% • Elective surgery, achieved by simple transfusions • Urgent surgery, achieved by exchange blood transfusion

Routine Preoperative Blood Transfusion in Children with SCD Is Not Recommended

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Why Should I Obtain the Certified Professional in Patient Safety (CPPS) Credential?

by Jonathan B. Cohen, MD, MS, FASA, CPPS, and Patricia A. McGaffigan, MS, RN, CPPS

Anesthesia professionals have a long history of paving the way in patient safety. The Anesthesia Patient Safety Foundation was launched in 1985, four years before the publication of *To Err is Human*, and twelve years before the founding of the National Patient Safety Foundation.[1-3] Significant progress has been made in patient safety over the past several decades, but there is growing evidence that continued progress in harm reduction has stalled.[4-7] Further, despite the advancements that have made the delivery of anesthesia safer today than it has ever been, knowledge of the science underlying patient safety is not instinctual and not always straightforward. Popular misconceptions that place greater emphasis on the need for human vigilance over the design of safe systems and cultures which support human performance have resulted in the persistence of adverse events (Table 1).

In order to overcome the misconceptions and inertia with progress in eliminating preventable harm, health care requires clinicians, leaders, and faculty who embrace a fundamental commitment to constancy of purpose for safety and demonstrate the requisite knowledge and competencies to lead and ensure this progress. Anesthesia professionals are optimally suited to leverage their profession's focus on patient safety to become health care leaders that shepherd the evolution of the field and organize safe systems of care. One such path for validating knowledge and competencies and advancing progress in safety is through formal certification in patient safety.

MISCONCEPTIONS ABOUT PATIENT SAFETY

Misconception	What is supported by safety science:
The creation of strict rules that everyone must abide by universally improves patient safety.	• While rules are necessary, rules alone are insufficient. • Rules often reflect *work-as-imagined*, a sometimes "pollyannaish" state of how tasks are envisioned to be accomplished versus *work-as-done*, which is how health care professionals must actually accomplish the tasks given the context and constraints of the complex work system. • Organizations often create so many rules that they encroach upon the space necessary to do daily work, conflict with other rules, and paradoxically lead to more adverse events.[8,9] • Violations of rules frequently precede adverse events, but they can also precede daily work without resulting in harm for many years. This is indicative of the importance of the adaptive capacity of health care professionals to their complex work environment.[10]
Punishment of individuals sends a clear message that safety violations will not be tolerated by an organization.	• Virtually all safety issues are heavily influenced by the systems in which the health care professionals work.[11] • Humans are incapable of error-free performance and admonitions to individuals to remain more vigilant are ineffective, as vigilance cannot be sustained indefinitely.[12-14] • A punitive approach to these events will not improve safety; rather systems need to be designed that support vigilance and create barriers, recoveries, and redundancies to mitigate harm.[13,14] • Punishing individuals for making errors leads to concealment, making it harder to detect areas in which systems improvement is necessary.[15,16]
Safety reporting accurately reflects the incidence of adverse events	• Safety reporting in health care was never intended to capture incidence.[17] • Reporting rates are determined by a wide range of cognitive, social, and organizational factors including ease of reporting and the perceived utility in reporting.[18] This may lead reporting to grossly underestimate the true incidence of adverse events and near misses.[19] • No single detection method will adequately capture the full range of adverse events; multiple methods are necessary.[20]

Table 1: Some Common Misconceptions About Patient Safety.

THE CPPS CERTIFICATION AND RE-CERTIFICATION PATHWAYS

In 2011, the National Patient Safety Foundation (which merged with the Institute for Healthcare Improvement in 2017), formed the Certification Board for Professionals in Patient Safety (CBPPS) to develop and oversee a program to credential individuals with knowledge and competencies in patient safety.[21] To date, more than 6300 professionals from all 50 US states and 32 countries have earned the Certified Professional in Patient Safety (CPPS) credential.[22] This professional certification program serves several purposes.[22] It establishes core standards for the field of patient safety, sets an expected proficiency level of those who practice it, and provides those interested in patient safety a way to demonstrate their knowledge and skill. It also serves to provide a means for employers and organizational leadership to validate a professional's competencies in patient safety. In 2023, the CPPS examination became the first and only certification examination dedicated to patient safety to be accredited by the National Commission for Certifying Agencies (NCCA).

To be eligible to sit for the CPPS certification examination, a professional must have at least a Baccalaureate degree and three years of experience in a health care setting or with a provider of services to the health care industry, or an associate degree or equivalent plus five years of experience. Those who are in training, or have recently completed training, may satisfy this requirement with time spent in clinical rotations and residency programs. The content of the domains covered by the examination was originally developed in 2011 after an initial job analysis of patient safety professionals was conducted. The purpose of the job analysis, which is repeated over time, is to identify the practice, knowledge, and tasks associated with professional certification in patient safety and to inform a relevant, valid certification examination that is supported by evidence. While the first CPPS job analysis was informed primarily by survey respondents from within the United States, subsequent job analysis surveys have widely incorporated feedback on practice from diverse respondents from around the world. The current CPPS examination includes the five domains of culture, leadership, patient safety risks and solutions, measuring and improving performance, and systems thinking and design/human factors.

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CPPS Credential Recognizes Skills and Knowledge in Patient Safety

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Additional information about the CPPS certification examination and recertification requirements is available in the **CPPS Candidate Handbook** at https://forms.ihi.org/hubfs/CPPS/CPPS%20Candidate%20Handbook%20April%202023.pdf.[23]

The CPPS certification examination, practice examination, and recertification programs are overseen by the CBPPS. The CPPS review course, offered by IHI, is separately developed, offered, and taught by subject matter experts, who are unaffiliated with the CPPS examination to create a firewall and ensure integrity between the preparation and examination activity. The CPPS review course is offered in multiple formats, including live in-person and virtual sessions, and a self-paced, online format. Additional information about the **IHI CPPS review course** is available at https://www.ihi.org/education/cpps/review-courses.[24]

Much like the practice of anesthesiology, patient safety is a science, and knowledge of best practices continues to evolve. Lifelong learning in patient safety is essential. Maintenance of the CPPS credential indicates that those who have the certification remain current in this knowledge. Recertification follows a three-year cycle, and there are two approved pathways that can be taken: 1) earning 45 continuing education or experiential hours in content areas that align with the domains that comprise the current CPPS certification exam or 2) retaking and passing the CPPS certification exam within a year prior to the expiration date. Anesthesia professionals have access to a significant amount of continuing education material offered by professional societies both online and at conferences and meetings that meet the criteria for the first recertification pathway.

THE EVOLUTION OF CPPS CERTIFICATION

In the early years of CPPS certification, exam candidates were primarily US-based, and more highly experienced and tenured patient safety, quality, and risk officers or leaders. Since the first exam was offered in 2012, diverse candidates from a variety of roles, specialties, and geographies have earned the CPPS credential. This includes health care executives, clinical department leaders, and direct patient care providers and clinicians across the continuum of care, as well as colleagues from medical technology companies, accreditation organizations, quality and safety associations and agencies, consultants, and patient and family advocates. Examples of specialties include anesthesiologists, CRNAs, surgical, perioperative, critical care, and pain management staff.

EXAMPLE OF CPPS INTEGRATION INTO MEDICAL EDUCATION

The CPPS review course and exam are increasingly incorporated into graduate medical, nursing, and safety and quality education. Inspired in part by the Lucian Leape Institute's report *Unmet Needs: Teaching Physicians to Provide Safe Patient Care*, the leaders of the University of North Texas Health Science Center's Texas College of Osteopathic Medicine restructured their curriculum to prepare graduates with demonstrated knowledge and competencies in safety.[25] In the three-year period since integrating the CPPS review course into their third-year curriculum, 27 academic leaders and faculty and nearly 850 students have earned the CPPS credential, entering residency more prepared to practice safely and serve as advocates for patient safety. More graduate programs in health care are integrating the CPPS review course into their curriculum offerings.

THE VALUE OF CERTIFICATION IN PATIENT SAFETY

Individuals pursue certification in patient safety for a range of reasons, including personal and professional recognition of their knowledge and competencies. In recent years, the CPPS credential has become a requirement upon hire or within the first year of employment, especially for safety, quality, and risk positions to distinguish their capabilities from other candidates. Seventy-nine percent of those who have earned the CPPS credential report that it has helped them improve patient care at their organization, and 81% report that they have led organization, or system-wide initiatives, leading to critical improvements, since earning the CPPS credential.[22]

Specific examples include leading opioid and other medication safety initiatives, developing sedation and monitoring guidelines, collaborating with risk management and quality/safety departments to educate on just culture, safety reporting and risk reduction strategies, and reengineering undergraduate medical school and other safety education programs.

Although quality improvement and patient safety have been combined over the years, it is increasingly recognized that the skills necessary to become a leader in patient safety are distinct from those necessary in quality improvement.[26,27] The rapidly evolving health care landscape offers expanded opportunity for anesthesia professionals to contribute their safety expertise across new and diverse roles and settings of care. The CPPS credential is distinct in that is the only certification that recognizes professionals' skills and knowledge specifically in the field of patient safety. In 2007, Paul Batalden and Frank Davidoff challenged us in health care to not only do our work every day, but to improve upon it.[28] The CPPS credential, through its evidence-based identification of relevant safety domains, testing of candidate knowledge, and requirement for continuing education or demonstrated experience in safety, provides both the map and the destination for developing professionals dedicated to improving patient safety.

As a result of the collaborative efforts of the APSF, ASA, IHI, and CBPPS, a CPPS review course will be offered at the 2024 ASA Annual Meeting in Philadelphia, PA, in October, and a discount is available to anesthesia professionals who elect to take the CPPS examination.

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Lifelong Learning in Patient Safety is Essential

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Wiretap Laws: Relevance to Clinical Practice and Patient Safety

by Karolina Brook, MD, FASA, CPPS

INTRODUCTION TO WIRETAPPING LAWS

In the United States, many federal and state laws have connections to patient safety of relevance for anesthesia professionals (including, but not limited to the various public health laws,[1] the United States' Patient Safety and Quality Improvement Act of 2005,[2] and peer review law[3]). A recent publication on wiretap laws and the perioperative physician in the *Journal of Clinical Anesthesia* highlights an important legal concept that has potential applications to both routine clinical practice and patient safety.[4]

Wiretapping laws or "eavesdropping" statutes govern whether an audio recording—of face-to-face conversations, telephone calls, or any other oral or wire (hence the name) communications— was made legally. Most of the wiretapping statutes in the United States were passed in the 1960s and 1970s, when accessibility to recording devices was not as prevalent. These laws still remain in place today with some amendments and modifications, at a time when easily concealable recording devices (namely, our cellphones) are ubiquitous.

Within the United States, wiretap laws vary from state to state and can be classified as being one-party, all-party, or "mixed." One-party consent jurisdictions require only one party to consent to an audio recording, whereas all-party consent jurisdictions require all present parties to consent. It is worth emphasizing that "all-party" is truly descriptive; if not all parties consent to the audio recording, either the recording has to cease, or the nonconsenting party has to remove themselves from the area of recording.[4]

Thirty-seven states require one-party consent, nine require all-party consent (California, Florida, Illinois, Maryland, Massachusetts, Montana, New Hampshire, Pennsylvania and Washington), and the remaining four (Connecticut, Michigan, Nevada, and Oregon) have mixed wiretap statutes (Figure 1).[4] Depending on the state, criminal punishments are classified as felonies or misdemeanors, and include fines ranging from $500 to $100,000, incarceration (ranging from 6 months to 20 years), or both. Civil recoveries range from $100 to $25,000, or recovery of civil remedies including damages, attorney fees, and litigation costs are also possible.[4]

Wiretapping laws are distinct from the Health Insurance Portability and Accountability Act (HIPAA), which protects *patients* from being photographed or videotaped.[5] While there are potential situations where both laws may be applicable, wiretapping laws apply to the unconsented *audio* recording of *any* individual, including clinicians. For example, patients or family members can record clinicians, clinicians can record patients, clinicians can record one another, or nonclinical hospital employees could make a recording—and all of these situations may consequently be subject to the various states' wiretap statutes.

Additionally, clinicians must be aware that even if a recording is made without appropriate consent, that recording may *still* be admissible in court—with the proviso that the recorder may be deterred because, in so doing, they would be submitting evidence that, in some states, constitutes a felony, and may subsequently be charged with violation of a wiretap statute.[4]

While hospital policy may help guide clinicians and patients as to how to act when faced with a recording or a request to record, the relevant state law trumps hospital policy. In other words, even if a hospital allows audio recording, the individuals are ultimately subject to the applicable state's wiretapping laws regarding the legality of a recording.

APPLICABILITY TO CLINICAL WORK AND PATIENT SAFETY

Audio recordings have many potential safety implications. Anesthesia professionals, who work in multiple areas of the hospital may be exposed to audio recordings at any time. For instance, with the ubiquity of cellphones, patients may wish to make audiovisual recordings of clinic visits, provider instructions (such as discharge instructions), discussions held during rounds (such as in the intensive care unit), or certain events in the hospital, such as the birth of their child.[6-8] These recordings can certainly be valuable: patients can improve their recall and understanding of the discussed medical information, and can share the information with family members.[8,9] When patients share an understanding of their medical care and have the support and encouragement of their family members, this has the potential to improve compliance with medical instructions. Additionally, allowing patients to record clinical interactions may theoretically improve the patient-clinician relationship, increase the patient's trust in the anesthesia professional, and may also make them more likely to follow medical instructions.[10] Compliance with medical instructions is associated with improved patient outcomes across multiple medical specialties and health care measures.

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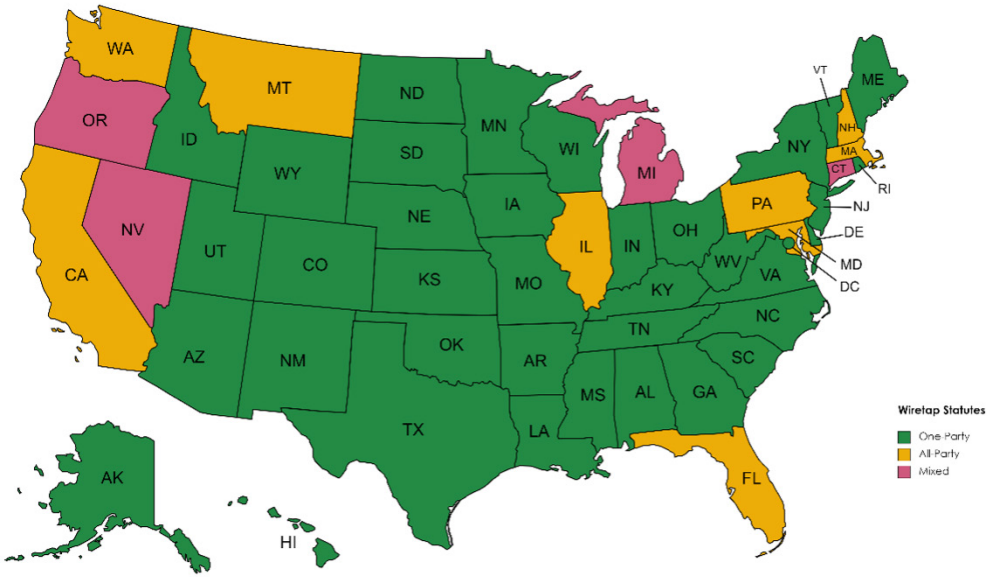

Figure 1: Classification of wiretap statutes as one-party, all-party or mixed, based on "Wiretap laws and the perioperative physician—the current state of affairs." de Menses et al. J Clin Anesth. 2023.[4] Map created using mapchart.net

Wiretap Laws Vary from State to State

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Patients who do not share the same language as their health care provider are particularly vulnerable. Recording the interaction, including the interpretation, allows patients to carefully listen to the translation and potentially even verify the accuracy of the interpretation.

Telemedicine and medical transcription services, used in areas such as intensive care units or in clinics, have burgeoned since the pandemic. The use of these services have their own implications on patient safety, such as increasing accessibility for patients who may be remote from care.[11] However, all of these services need to take into account relevant wiretap laws.

Similar to the desire to record egregious incidents in the community (such as interactions with police and other public officials), patients and clinicians may wish to record a clinical event in the hospital. This may include an unprofessional interaction, medical error, or an adverse event. Awareness of an event may induce change for the better and may improve patient safety. While wiretap laws may restrict such recordings, it is important to bear in mind that laws can change. For example, in Massachusetts, which has one of the strictest all-party wiretap consent laws in the country, allowing the recording of police is currently being contested in the courts.[12] Similarly, wiretap laws in all-party consent states could be amended to allow recording adverse events in clinical situations, with the goal of improving patient safety.

Additionally, there are various published initiatives that advocate recording clinical practice to improve patient care and safety: for instance, to allow families to watch surgeries as part of family- and patient-centered care.[13,14] Another example is in the use of an operating room Black Box to record surgeries with the intention of characterizing intraoperative errors, events, and distractions.[15] Such technology has the potential to improve care and patient safety by decreasing medical errors or improving communication. Importantly though, wiretap laws still remain applicable. For example, using a Black Box in an all-party consent state becomes legally complicated, as all present parties (which may change over the duration of the surgery or recording) need to consent to being audio recorded; the hospital cannot provide blanket consent. Clinicians that do not consent would need to leave and may need to be replaced, which has vast implications given current physician and nursing staffing shortages.[14] A potential solution is to exclusively utilize image-recording and not audio recording, recognizing that this would limit the ability to characterize communication errors.[14]

In summary, anesthesia professionals in daily practice, as well as any patient safety and quality improvement initiatives that leverage the use of audio recording, should all take into account relevant state wiretapping laws, and the legal limitations to audio recordings they pose.

PRACTICAL SUGGESTIONS

Many may feel that if the *intention* behind the recording is good—for example, if it is made for personal private use, or to capture (and later report) an error, adverse event, or hostile interaction—the recording may be warranted. However, if the appropriate consent is not obtained prior to making an audio recording, it potentially demonstrates violation of a state's wiretap laws. As an illustrative example, when a high school student in an all-party consent state recorded a bullying incident and presented the video to their school principal, they were charged with violation of their state wiretap law.[16] While those charges were later dropped, this example highlights that audio recording without appropriate consent can be contrary to the law.

While there may be scenarios where anesthesia professionals can expect to address wiretap laws (such as in the case of medical transcription), there are many times the wiretap laws can become relevant unexpectedly. It can be challenging to step away and consult legal help, and consequently it is imperative that all clinicians are not only aware of and understand how their state's wiretapping laws affect audio recordings, but also how they may choose to respond to a particular situation. Some individuals may feel indifferent to being recorded, while others may be strong advocates of being recorded; these feelings can change depending on the situation at hand.

The following are some hypothetical situations where wiretapping laws may apply as well as recommendations for how to react. These recommendations are a balance of multiple factors, including educating all present about the law (since most individuals tend to be unaware of wiretapping laws), allowing those involved to make a decision regarding their legal rights, and maintaining the patient-clinician relationship.

Situation 1: You are the anesthesia professional wheeling a patient into the operating room. You notice a film crew videotaping you as you walk in. When you inquire about the filming, the surgeon informs you that they are there to film the entire surgery, including aspects of the anesthesia care "to improve safety." They've "already obtained consent from everyone," but this is the first time you are learning about this.

Situation 2: You are placing an epidural for a laboring patient. The significant other has remained in the room, as is customary at your institution.

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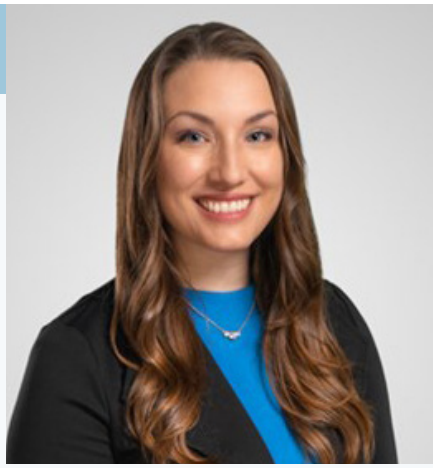

Amy Pearson, MD, APSF Director of Digital Strategy and Social Media.

Anesthesia Professionals Need to Be Aware of Wiretap Laws

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As you complete the procedure and prepare to administer the test dose, you look up and notice the significant other is standing to your side and is holding up their cellphone which is pointed at you. You ask whether they have been filming, to which they respond uncomfortably that they are not, and put their phone away.

Situation 3: You are seeing patients via telemedicine in your chronic pain clinic. You discuss the use of medical transcription services with your next patient. They provide consent to being recorded, after which they ask if they, too, can record the clinic visit for their own personal use.

Suggestions: If aware of a video recording (Situations 1, 2 and 3), we recommend verbalizing that the recording is occurring. In an all-party consent state, it may be helpful to inform all present that every person has to consent. For example: "I see that you are recording. In our state, everyone present has to consent to recording. I do/do not consent to recording." If all parties do not consent to being recorded, either the recording has to stop, or those who do not consent have to leave the area. Individuals who feel uncomfortable with being direct may find it useful to cite hospital policy (if one exists at their institution): "It is hospital policy not to allow video recordings." While citing hospital policy can be helpful to diffuse an uncomfortable situation, bear in mind the hospital cannot consent on others' behalf (Situation 1).

In the situation where the individual is lying about recording or is secretly recording (Situation 2), it can still be helpful to state whether you do/do not consent to being recorded. While the recording may be admissible in court, the individual may be deterred from doing so as they would be submitting evidence that they may have violated a state law (particularly if in an all-party consent state).

It may be helpful, particularly if in a one-party consent state (where the recording individual has the right to record even without everyone's consent), to explore the reasons why the individual is pursuing the recording (Situations 2 and 3), and to suggest alternate ways to provide them with this information (such as requesting their medical records).

In the situation of medical transcription (Situation 3), we recommend similarly informing all parties about the recording and obtaining consent, particularly since the parties may be in different states, which could include an all-party consent state. Depending on the locations of the respective individuals (i.e., the patient(s) and clinician(s)), one-party or all-party wiretap laws may apply.[4]

Deciding whether to consent to a recording is up to each individual person. We feel it is important to bear in mind the relationship with the recording individual, whether there are alternative ways to provide satisfactory information that do not entail recording, and how likely consenting to being recorded may end up in litigation—something that, in reality, is completely out of your control once you consent to being recorded.

CONCLUSION

While currently all of the described situations are potentially governed by wiretapping laws, as technology continues to improve, there may be additional scenarios where wiretapping laws could become applicable. Therefore, in the daily practice of anesthesiology, and additionally in considering initiatives that may involve audio recording, all anesthesia professionals need to be aware of wiretap laws, how a particular state's laws may impact the legality of any audio recordings, and the potential criminal punishments and civil remedies that can be imposed for violations. Unless a major overhaul of United States wiretapping laws were to occur, it behooves all anesthesia professionals to be well versed in the multitude of situations where wiretap laws are or could be applicable, and how they would react to these scenarios.

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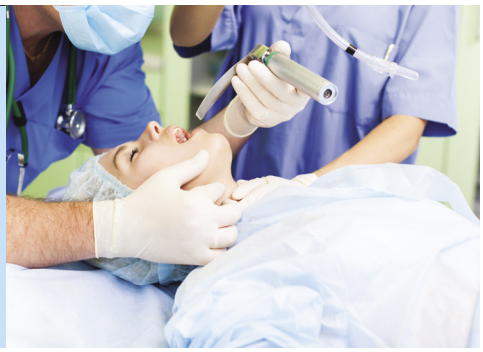

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