

## Alarm Fatigue and Patient Safety

by Keith J Ruskin, MD, FAsMA, FRAeS, and James P Bliss, PhD

### INTRODUCTION

Electronic medical devices are an integral part of patient care, providing vital life support and physiologic monitoring that improve safety throughout hospital care units. The alarms and alerts generated by such devices are intended to warn clinicians about any deviation of physiological parameters from their normal values before a patient can be harmed. Life support devices (e.g., ventilators and cardiopulmonary bypass machines) also employ alarms to alert health care providers to potentially life-threatening failures. These two alarm types (i.e., physiologic and device function) lead to a high frequency of alarms in the clinical setting. For example, in one study of patients undergoing procedures, 8,975 alarms occurred during 25 consecutive procedures. An average of 359 alarms were recorded during each procedure, or approximately 1.2 alarms per minute.<sup>1</sup> Equipment manufacturers deliberately set alarm defaults to high sensitivity, so that true events are not missed. The result is that most alarms have low specificity and low positive predictive value and are often ignored.<sup>2</sup> This problem is compounded when alarms are implemented across multiple parameters, leading to a cascade of alarms that create a noisy, distracting environment while doing little to improve patient care.

*Alarm fatigue* refers to an increase in a health care provider's response time or a decrease in

his or her response rate to an alarm as a result of experiencing excessive alarms. Alarm fatigue is common in many professions (e.g., transportation and medicine) when signals activate so often that operators ignore or actively silence them. The organizational and technological aspects of the hospital environment are highly complex, and alarm fatigue has been implicated in medical accidents.<sup>2</sup> The Joint Commission, recognizing the clinical significance of alarm fatigue, has therefore made clinical alarm management a National Patient Safety Goal. This article will provide an overview of signaling (alarms, alerts, and warnings) and offer practical solutions to reduce alarm fatigue in the operating room and intensive care unit.

### FALSE, NONACTIONABLE, AND NUISANCE ALARMS

Researchers have historically used signaling terms interchangeably, which can complicate attempts to understand and address the problems created by excessive alarms. Bliss and Gilson proposed an early taxonomy of signaling terms that accounts for the timing between a signal and its associated situation.<sup>3</sup> They adopted the term "signal" as an umbrella term for all stimuli that serve the general function of emergency notification. This taxonomy defines an "alarm" as a transient sensory signal (usually auditory or visual) that indicates an ongoing danger that requires an immediate corrective action, while an "alert" indicates that an adverse event may occur in the future.<sup>3</sup> For example, an alert may occur ten minutes before a patient is expected to deteriorate while an alarm might indicate asystole. Alerts give the operator more time to react, allowing a preemptive response that may allow the problem to be avoided, while a response to an alarm takes place when the danger exists and is reactive or corrective.

The current standard for medical alarms is IEC 60601 1-8, which specifies basic safety and performance requirements, including



alarm categories that are prioritized by degree of urgency, and consistency of alarm signals.<sup>4</sup> The IEC standard does not, however, address the problems associated with the high sensitivity of sensors and low specificity of alarm conditions. A valid alarm may give the health care provider very little time to react to a life-threatening event. In general, signals should ideally give a health care provider enough time to take an action that will prevent an adverse outcome. The duration of an appropriate time delay is, however, contingent upon operational parameters, most notably the rate at which the situation is expected to deteriorate.

Medical signals can be further subdivided according to their underlying condition. *Clinical alarms* indicate that the patient requires immediate attention, while *technical alarms* indicate that the biomedical equipment requires attention. For example, ventricular fibrillation results in a clinical alarm, while a disconnected sensor or a poor-quality blood pressure tracing might cause a technical alarm. Xiao and Seagull have proposed a taxonomy that distinguishes among alarms based on their usefulness for medical personnel who monitored clinical processes (Table 1).<sup>5</sup>

Actionable alarms indicate a physiologically abnormal state, which requires that the anesthesia professional intervene in order to avoid patient harm.

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### To Our AANA Readers

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**Table 1: Xiao and Seagull's taxonomy of alarms:<sup>5</sup>**

<b>False alarms</b> occur when no danger exists, often because sensor thresholds are set too conservatively.
<b>Nuisance alarms</b> may indicate a problem in a specific context, but they have been activated in a different context (e.g., an arterial catheter low pressure alarm that activates when a blood pressure cuff is inflated).
<b>Inopportune alarms</b> occur at the wrong time, perhaps as alerts that signal a condition far in the future.

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- (1) **Review articles or invited pro-con debates** are original manuscripts. They should focus on patient safety issues and have appropriate referencing (see <https://www.apsf.org/authors-guide/>). The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.
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- (3) **Letters to the editor** are welcome and should be limited to 500 words. Please include references when appropriate.

- (4) **Rapid Response** (formerly Dear SIRS) The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the Committee on Technology, oversees the column and coordinates the readers’ inquiries and the response from industry.

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

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# Safety in Non-Operating Room Anesthesia (NORA)

by Jason D. Walls, MD, and Mark S. Weiss, MD

## INTRODUCTION

As case volumes increase year after year, Non-Operating Room Anesthesia (NORA) continues to evolve,<sup>1</sup> with NORA-based procedures comprising a larger share of modern anesthesia practice than ever before.<sup>2</sup> Growth in NORA-based procedures can be attributed to many driving influences, including the advent of less invasive procedures, an aging population with increasing comorbidity burden, the introduction of new technology expanding the indications for and complexity of NORA cases, and the economics of a health care environment that looks to improve value by decreasing costs. With these advances and growth, new demands on the anesthesia team are challenging conventional methods. Increasingly, NORA cases may require more invasive monitoring techniques and deeper levels of sedation that carry the potential for increased patient risk and injury. As Woodward et al. noted, we are seeing an “evolution in patient and procedure complexity in NORA.”<sup>3</sup>

## CLOSED CLAIMS DATA

Examination of closed claims databases provides insight into the potential adverse outcomes and vulnerabilities related to NORA procedures. The majority of NORA closed claims cases originated in the gastrointestinal endoscopy suite.<sup>3</sup> This might be related to the sheer volume of cases performed there as compared to other venues.

Patients undergoing NORA procedures, compared to those performed in the operating room, have a higher frequency of severe injury and death.<sup>4-6</sup> In more than half of NORA-related claims involving deaths, patients were deemed to have received substandard anesthesia care preventable by improved monitoring techniques.<sup>5</sup> Suboptimal care and failure to provide safe practice were seen as the leading cause of poor outcomes.<sup>3</sup> Most claims were related to respiratory events, specifically inadequate oxygenation and/or ventilation.<sup>5,6</sup> Monitored anesthesia care was the most common anesthetic technique used, contributing to 50% of claims.<sup>5</sup> Oversedation leading to respiratory depression was implicated in a third of all claims. In most claims related to oversedation, there was limited use of monitoring expired carbon dioxide or any respiratory monitoring at all.<sup>5,6</sup>

## HOW RISKY IS NORA?

Despite intriguing findings from the closed claims work, there remain limited data related to NORA-based outcomes, confounding efforts to mitigate risk and improve safety.<sup>5,6</sup> Conventional teaching has been that patients have increased risk with NORA-based procedures compared to those done in the traditional operating room. However, recent findings from the National Anesthesia Clinical Outcomes Registry (NACOR) suggest that NORA-based proce-



A Computed Tomography (CT) Scanner Area



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dures, as a whole, have a lower rate of complications, morbidity, and mortality compared to traditional operating room procedures.<sup>2</sup> Importantly, though, NORA venues may differ in the frequency of adverse events. Specifically, Chang et al. observed a higher incidence of complications and higher mortality in patients undergoing NORA procedures in the cardiology and radiology suites as compared to the operating room or the gastroenterology suite.<sup>2</sup> This analysis did not control for differences in

age and comorbidity burden, so caution should be taken interpreting the findings.

Both NORA-specific and more general procedural issues influence the risk of NORA-based procedures (Table 1). NORA-specific issues are related to concerns within the NORA suite itself, including location and procedure-related challenges. NORA procedures are often performed in crowded rooms with limited patient access. These rooms may not have been originally designed for an anesthetic. They may be retrofitted with outdated anesthesia equipment. They may be small in size with an inadequate power supply and may be equipped with poor lighting. Additional issues to address in NORA procedures are supply lines of equipment (e.g., appropriate monitoring devices) and the adequacy and availability of support staff. NORA cases are also more likely to start after normal working hours compared to the operating room.<sup>1</sup> These “off-hour” starts may limit the availability of critical resources and force unfamiliar personnel to assist with the procedure and anesthesia. Also, compared to the traditional operating room, a greater percentage of NORA procedures are being performed on an emergency basis.<sup>6</sup> Whether off-hour starts and emergency status translate to poorer patient outcomes is unknown.

**Table 1: Challenges to providing safe care in NORA settings**

NORA-specific challenges
Remote location far from pharmacy and supplies
Noisy environments
Limited workspace, small procedure room
Inadequate lighting
Minimal temperature regulation
Electrical / magnetic interference
Older, possibly unfamiliar equipment
Lack of skilled anesthesia support staff
Limited patient access during procedures
Inadequate power supply
Radiation safety
Challenges relevant to NORA and OR anesthesia
Supply of equipment
Appropriate monitoring devices
Inadequate support staff
Patient-related illness
More cases after normal working hours
Increased percentage of “emergency” procedures

## PATIENT ISSUES

Statistically, the NORA patient population is older than the population of patients undergoing traditional surgery in the operating room, and the average age of NORA patients is increasing more rapidly than in the group undergoing traditional surgery. NORA patients also tend to be more medically complex than those in the traditional operating room cohort, adding to overall patient risk.<sup>1,6</sup> A greater percentage of patients receiving NORA are classified as ASA physical status III-V compared to those in the traditional operating room.<sup>1</sup> Often these patients are not candidates for traditional

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# NORA Related Complications May Be Prevented Through Vigilant Monitoring

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operative procedures and their only option is a NORA intervention.<sup>2</sup>

As the number of older and medically complex patients receiving NORA grows, the anesthesia team must maintain an emphasis on the preprocedure evaluation for assessment of patient safety and procedural feasibility. Our ability to adequately assess these patients prior to their procedure may be limited or difficult, as many clinicians performing NORA procedures do not have either a pre-operative clinic or the dedicated space to examine patients preoperatively. Patient-specific comorbidities unique to each NORA specialty must be assessed prior to every procedure. For example, the anesthesia professional must evaluate the impact of esophageal stricture or reflux prior to endoscopy, the significance of heart failure prior to an electrophysiology study, or the severity of obstructive sleep apnea prior to an MRI study in which the ability to rapidly address airway obstruction may be limited. NORA patients may be critically ill, and procedures may need to be performed emergently. This urgency may result in a diminished ability of the patient to provide informed consent. Invasive monitoring may be necessary and should be prepared and available when needed. Fasting status must be evaluated prior to every procedure and must be considered when prescribing an anesthetic technique.

Additional concerns across the NORA spectrum include airway management during procedures that require a shared airway. Some procedures may involve placing the patient in a position other than supine, such as the prone and lateral positions for various gastrointestinal procedures, including colonoscopy and endoscopic retrograde cholangiopancreatography. In all situations, an emphasis must be placed on real-time communication between the anesthesia team, the proceduralist, nursing and other support staff. Open, multidisciplinary communication should begin prior to the start of the procedure (e.g., to discuss anesthetic choice and safety concerns), continue through the procedure, and into the recovery area always emphasizing patient safety.

## PERSONNEL/SUPPORT TEAM ISSUES

The traditional operating room is an area that has clearly delineated roles and practices. Anesthesia professionals are specifically trained to operate within this area. In contrast, non-operating procedure rooms are usually individualized and customized for specific procedures. Personnel working in the NORA environment may be unfamiliar with operating room protocols and be uncomfortable or unfamiliar with patients under anesthesia. They may have a focused medical or clinical background and are unfamiliar with anesthesia related problems and emergency protocols. Similarly, the anesthesia team may be treated as “outsiders,” in that they may not be



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familiar with a specialized facility, its environment, staff organization, and workflow. Open, free communication among the staff is paramount to safe practice, and barriers to sharing information should be identified and addressed. Compliance by staff to patient safety protocols should be augmented by regular instruction and evaluation.

## EQUIPMENT AND MONITORING

NORA equipment and monitoring should be held to the same standards as the traditional operating room. Appropriate equipment and standard monitoring are key to safety in the NORA suite. NORA cases are often performed in remote locations far from needed resources and with varying levels of typical anesthesia equipment. Anesthesia equipment may be outdated or retrofitted and, as previously stated, optimal workspace and patient access can be limited by both the actual procedure being performed and the physical constraints of the NORA room.<sup>6</sup>

In 2013, the ASA published guidelines to encourage safe, high quality care for NORA locations.<sup>7</sup> These guidelines provide anesthesia professionals with minimum standards to providing safe care by mandating the use of standard monitoring equipment similar to the traditional operating room including monitoring oxygenation, ventilation, circulation and temperature.<sup>8</sup> When providing NORA, anesthesia professionals should demand appropriate time to setup and check all necessary equipment and have access to the necessary resources to provide safe NORA. Improperly functioning equipment, suboptimal workspace, and inadequate support should not be tolerated in the NORA suite.

## IMPROVING PATIENT SAFETY FOR NORA PROCEDURES

As NORA grows, patient safety and the quality of anesthesia provided must continue to be emphasized to decrease risk to patients. Reasonable first steps to improve patient safety for NORA cases include adequate case preparation and a familiarization with the location, equipment, and available staff. Overall, the anesthesia provider must work with the procedural team to assure the safety of the NORA environment for patient care. Additional preparation measures should include the routine maintenance of all anesthesia related equip-

ment, an adequate supply of rescue medications, and the development of appropriate safety protocols. Establishing protocols for emergency procedures as well as establishing an appropriate response to adverse events add to the safety of NORA based practice.

Recent evidence strongly suggests that many NORA-related complications would be prevented through appropriate, vigilant monitoring and maintaining the same standard of care as used in the operating room.<sup>2</sup> As stated above, a closed claims analysis showed that the majority of adverse outcomes in NORA are related to respiratory depression and inadequate monitoring. ASA monitoring standards should be instituted in all NORA environments whenever feasible, specifically emphasizing the assurance of adequate ventilation through clinical evaluation and monitoring expired carbon dioxide. As in the operating room, protocols and checklists ensuring the availability of personnel and equipment may help to standardize care to produce reliable and consistently safe results. These measures are helpful to manage both familiar and unfamiliar cases and may aid in providing uniform care even with unfamiliar staff. Each step of every protocol and pathway must be evaluated to create a consistent, safe, and uniform NORA environment for both practitioners and patients.

Adverse events can occur despite our best efforts to anticipate and prevent them. When these events do occur, it is essential to have a system in place to examine them and prevent future occurrences. Such a system must rely on a method to define and examine potential errors and near misses. Such systems should be proactive, rather than reactive. Quality improvement programs should be established and reinforced by debriefings, root cause analysis and continuing education programs.

## THE FUTURE AND BEYOND

With the continued growth of NORA creating novel, complex procedures and utilizing advanced technology that require new and deeper levels of sedation, anesthesia professionals are well positioned to guide a multidisciplinary team approach, to improve practice, to increase value, and maintain patient safety.

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# Alarm Fatigue

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A mild deviation might require only assessment of the patient and heightened alertness for further change, while others might indicate an urgent, life-threatening problem.<sup>6</sup> Nonactionable alarms can be caused by monitoring artifact (e.g., electrocautery causing a “ventricular fibrillation” alarm), or a true deviation from the alarm limits that represents a clinically insignificant abnormality (e.g., a ventilator’s apnea alarm activating while the patient is being intubated).

### ALARM FATIGUE

Failure to respond to an alarm can cause patient harm and may potentially be life threatening. The United States Food and Drug Administration (FDA) reported over 500 alarm-related patient deaths during a five-year period, and many believe that this report significantly underestimates the magnitude of the problem.\* The purpose of an alarm is to get the immediate attention of a person when an abnormal event occurs; alarms are therefore designed to be intrusive and distracting. Frequent interruptions from nonactionable alarms can degrade prospective memory, and there is evidence that improving the design of alarms and alerts can prevent errors.<sup>7</sup> Health care providers may become desensitized to frequent false alarms; this is called the *cry-wolf effect*<sup>8</sup> and is more likely to occur during periods of high workload.<sup>9</sup> The cry-wolf effect may lead users to mistrust and possibly ignore subsequent alarms from the same or similar devices.

The intrusive nature of auditory alarms can increase the stress level during an abnormal event.<sup>10</sup> In 2015, one of the authors (KJR) defined *alarm flood* as a large number of alarms, some of which may be in a different patient care area.<sup>11</sup> Further, alarms can disrupt sleep and contribute to ICU delirium. Hall et al. measured the stress response to an “emergency” alarm that required the participants to immediately get dressed and walk briskly to a testing room. They found that the physiologic stress (as indicated by saliva cortisol level) caused by nighttime alarms was significantly greater than those that occurred during the day.<sup>12</sup>

### SOLUTIONS: SIMPLE AND COMPLEX

Alarm fatigue is a complex problem, and potential solutions include redesigning organizational aspects of unit environment and layout, workflow and process, and safety culture. Technical and engineering solutions, workload considerations, and practical changes to the ways in which existing technology is used can mitigate the effects of alarm fatigue. These changes will ultimately require new approaches to training, clinical workflow, and organizational policies.<sup>11</sup>

The overarching goals for a comprehensive solution to alarm fatigue should be to clearly and accurately indicate potential hazards while minimizing false or nuisance alarms. Signals should be consistent across all equipment used in the health care environment. Multiple factors, including noise, lighting, competing task demands, distrust, and inattentive blindness or deafness can prevent a health care provider from detecting or responding to an alarm. New equipment should incorporate designs that decrease a clinician’s workload and do not unnecessarily distract him or her from other time-critical tasks. Both increasing workload and high levels of ambient noise can impair subjects’ ability to localize alarms.<sup>13</sup>

Changes to the alarm processing algorithms of physiologic monitors can reduce the number of nonactionable alarms. Delaying alarm activation for short, clinically-irrelevant violations can improve alarm reliability. One study hypothesized that implementing a short alarm delay for minor threshold violations (which the researchers defined as a deviation less than 4% beyond the threshold) would inhibit alarms caused by



brief, clinically irrelevant violations.<sup>14</sup> The delay allowed the values to return to normal limits before the alarm was activated. Implementing this delay for alarms that transiently violated limits by a small amount resulted in a 74% reduction in false alarms.<sup>14</sup> Srivastava et al. used a machine learning algorithm to simultaneously analyze the electrocardiogram, pulse oximetry, and arterial blood pressure waveforms. Their model was able to suppress 77% of false alarms while improving alarm accuracy to 84%.<sup>15</sup> These studies and others highlight the opportunities for medical equipment manufacturers to develop innovative algorithms to increase the positive predictive value of clinical alarms.

Reducing alarm volume can alleviate the level of noise pollution in the operating room and intensive care unit. Conventional wisdom suggests that alarms should be as loud as possible to immediately attract the attention of the operator. In one recent study, however, Schlesinger et al. found that physicians who were required to respond to simulated critical events while completing an auditory speech intelligibility test were

able to distinguish alarms even when they were -11 dB below the ambient noise level.<sup>16</sup> This could reflect the expertise level of the operators and suggests that it might be possible to reduce alarm volumes and thereby the overall noise level in health care institutions. Although alarms must be audible, this study suggests that reducing volume might be possible, especially for alarms that do not indicate a life-threatening condition. Strategies for doing so should be considered jointly with manipulations of signal wave form, intertemporal interval, and other physical parameters.<sup>13</sup>

Some simple interventions can be used immediately by nearly any clinician. Clinicians should choose appropriate alarm limits for each patient. Shanmugham et al. found that perceived workload was lower when alarm settings were modified to reflect an individual patient’s physiologic status as compared to an unmodified default clinical alarm setting.<sup>17</sup> The simple step of changing clinical alarm limits and disabling nonessential alarms improved the accuracy of alarm response, participants’ experience, and overall satisfaction. A simple way to accomplish this goal is to use specific profiles when available (e.g., use pediatric defaults when caring for a child and use the “paced” mode when a patient has a pacemaker or implantable cardiac defibrillator device). Disposable sensors may also be responsible for false alarms caused by artifact, especially when they are repositioned or allowed to dry. A sensor or cable that is not compatible with the monitor in use and electrodes with dried gel or adhesive may also trigger false alarms. A simple solution is to use new electrodes and to replace them rather than attempting to reuse them if they must be moved. Over-monitoring can also increase the number of alarms to which a clinician is exposed. The level of monitoring should therefore be selected to suit the needs of the individual patient.<sup>11,18</sup>

### CONCLUSIONS

Alarm fatigue is a multifaceted problem with multiple contributing factors, including false alarms, and nonactionable alarms. Most alarms are triggered when the value of a given parameter violates a preset threshold that is frequently set in anticipation that vital signs that are normal for a given patient will fall within a narrow, predicted range. Although this philosophy might work well when monitoring a single parameter with a well-defined normal range (e.g., oxygen saturation), it can also result in a significant number of false alarms when monitoring patients with multiple comorbidities in an actual clinical environment. Medical equipment manufacturers can help to solve this problem by developing innovative alarm processing algorithms. Clinicians can also make simple changes to their practice that will help to mitigate the effects of alarm fatigue.

\*The Joint Commission Sentinel Event Alert. Medical device alarm safety in hospitals. [http://www.jointcommission.org/assets/1/18/SEA\\_50\\_alarms\\_4\\_5\\_13\\_FINAL1.PDF](http://www.jointcommission.org/assets/1/18/SEA_50_alarms_4_5_13_FINAL1.PDF)

## Strategies to Reduce Alarm Fatigue

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## LETTER TO THE EDITOR:

### Drug Shortages: The Impact on the Patient/Anesthesia Professional Relationship

I challenge you to ask yourself some introspective questions regarding anesthetic practice: Do you feel your autonomy threatened? With the constant problems of drug shortages and allocation of precious resources, how does this impact the anesthesia professional/patient relationship?

In the February 2019 *APSF Newsletter* issue, the topic of drug shortages was covered. One aspect of this problem requires more attention: How do we take care of our patients without the intended medications available to us? Many anesthesia professionals are employed by health care systems today. With that in mind, what rights do we have to consider postponing or cancelling elective procedures until these shortages abate? Additionally, what responsibilities do we have to notify our patients of the shortages and the need to use “alternative” medicines? Should our employers bear that responsibility? Alternatively, should we both share the burden?

I would hope that many of us have already thought of these questions and dealt with them in a way that personally gives you comfort and peace. However, if you haven’t, my hope is that

this will inspire you to engage your colleagues to collectively determine appropriate solutions. Solutions that are keeping perioperative patient safety and quality of care as the end point. Involving everyone will ensure that whatever is decided, adequate supplies should be available.

Medicine is undergoing a tremendous evolution. Our relative autonomy feels threatened and, in many instances, we have become part of a collective business model to maximize profits. How we decide to accept and work within these parameters is individualistic. Nevertheless, it is imperative that our patients are always at the forefront of our practice. It is our responsibility to control and mitigate external factors and forces that constantly attempt to erode and threaten our commitment to patient safety and care.

*Respectfully submitted,  
Daniel J. Schoeck, MD  
Retired Anesthesiologist  
Toledo, OH*

*The author has no conflicts of interest pertaining to this article.*

## LETTER TO THE EDITOR:

## Hypoxia During Upper GI Endoscopy: There is Still Room for Improvement

*Editor's note: In this Letter to the Editor, a reader details the challenges in maintaining adequate oxygenation and ventilation during upper GI endoscopy. This topic is related to the feature article on Non-Operating Room Anesthesia in this issue of the Newsletter (see page 3).*

Upper endoscopies, even “simple” esophago-gastro-duodenoscopies (EGD’s), are challenging, potentially high-risk anesthetics for a number of reasons. They are by definition “shared airway” cases. They are also “reduced airway access” cases, since the patient is typically placed in the lateral, semi-prone, or prone position, greatly reducing the anesthesia professional’s access to the airway. Teeth can be dislodged by the bite block. Underlying pathologies (esophageal reflux, dysphagia, food impactions, GI bleeds, anemia, preparation for bariatric surgery) put these patients at risk for airway-related complications. Many are performed in procedure rooms with no anesthesia machine in case of an airway emergency and in locations remote from backup resources in the operating room. Rooms are darkened to allow the gastroenterologist a better view of the monitor screen. High case volume, quick case time, and room turnover pressures place time stress on the anesthesia professional, and can lead to the temptation to try to hurry the sedation, which can lead to “stacking” of doses of sedative agents, resulting in even deeper-than-desired levels of sedation. Computerized anesthesia records can create distractions for the anesthesia team, and can often force them to turn their back to the patient to face the computer screen.

Upper endoscopies often require very deep sedation bordering on general anesthesia to suppress the gag, cough, and laryngospasm reflexes, especially with initial insertion of the endoscope. Subsequently, the level of stimulation (and depth of sedation) can vary suddenly and significantly. Upper endoscopies are also, by definition, foreign body obstruction cases, since a large foreign body, the endoscope, is placed into the aero-digestive tract, often producing partial airway obstruction. Sedation reduces muscle tone of the upper airway, which may result in airway collapse that anesthesia professionals must commonly manage.<sup>1</sup>

The diameter of commonly used adult esophago-gastrosopes is 8.8-11 mm.<sup>2</sup> If we apply the formula for the area of a circle,  $A = \pi r^2$ , it becomes evident that the cross-sectional area of a 9 mm endoscope often exceeds the cross-sectional area of the airway documented on CT studies,<sup>3,4</sup> thereby presenting a risk for partial or even total obstruction of the airway in a significant percentage of patients. The Guardus® Overtube (US Endoscopy, Mentor, OH), a clear plastic tubular device placed over the endoscope to create aerodigestive separation for removal of

impacted food, has an even larger outer diameter of 19.5 mm.<sup>5</sup>

Another major challenge in delivering sedation for upper endoscopy has been the limitation of our supplemental oxygen delivery systems. Traditional oxygen facemasks for upper endoscopy are typically not used as they impair access to the mouth by the endoscopist. Often, the mode of oxygen delivery is one of our least effective: nasal cannula (or, insufflation via an oral catheter).

Standard nasal cannulae are recommended to be used at maximal O<sub>2</sub> flows of 5–6 L/min.<sup>6</sup> Even short durations of higher rates are not well tolerated because of discomfort and drying of the nares that may result in epistaxis. At O<sub>2</sub> flows of 6–7 L/min, nasal cannulae provide a maximum FiO<sub>2</sub> of approximately 0.44–0.62.<sup>6</sup> Other common clinical conditions, such as nasal congestion, nasal polyps, or septal deviation can further reduce the oxygen delivery from a nasal cannulae. By contrast, O<sub>2</sub> face masks with non-rebreathing reservoirs, at O<sub>2</sub> flows of 9–15 L/min, comfortably provide much higher FiO<sub>2</sub>’s of approximately 0.90–0.95.

Given the issues of airway encroachment and the potential for limited oxygen delivery, airway management during upper endoscopy under sedation is, by its very nature, “high risk.” Therefore, anesthesia professionals should approach these cases similar to the way we approach patients requiring general anesthesia in the operating room—by remembering the time-tested principles of “safe apneic time” and “maximal preoxygenation.”

“Safe apneic time” is defined as the delay from the onset of apnea until the SpO<sub>2</sub> drops to below 90%, into the steep portion of the hemoglobin-O<sub>2</sub> desaturation curve and into critically low levels. The safe apneic time in healthy adults is approximately less than one minute.<sup>7</sup> However, patients with decreased capacity for oxygen loading (e.g., anemia, pulmonary disease, obesity, decreased cardiac output, or decreased functional residual capacity), or with increased oxygen demand (fever, hypermetabolic state) desaturate much more quickly.<sup>8-10</sup>

It has been established for decades that the simple technique of “maximal preoxygenation” can double or even triple safe apneic time.<sup>7,9</sup> In a classic 1999 editorial in *Anesthesiology*, Dr. Jonathan Benumof wrote: “The purposes of maximally preoxygenating before the induction of general anesthesia are to provide the maximum time that a patient can tolerate apnea, and for the anesthesia professional to solve a cannot-ventilate/cannot intubate situation. Moreover, because a cannot ventilate/cannot intubate situation is largely unpredictable, the desirability to maximally preoxygenate is theoretically present for all patients.”<sup>10</sup> Dr. Benumof



Endoscopy Suite

vigorously espoused maximal preoxygenation whenever possible. Preoxygenation has become standard practice for many practitioners prior to all general anesthetic inductions (i.e., iatrogenically-induced apnea).<sup>8,9</sup>

There are several accepted methods of effective maximal preoxygenation.<sup>10,11</sup> Many techniques used by anesthesia professionals require O<sub>2</sub> flow (>10L/min) through a well-fitting oxygen mask. The most effective and efficient may be the “8 DB/60 sec” (8 deep breaths over 60 seconds) method described by Baraka.<sup>10,11</sup> Dr. Benumof’s logic, which has served our patients so well for decades in the potentially high-risk situation of induced apnea in the operating room, should be extended to patients undergoing upper endoscopy under sedation, particularly if this can be done simply and cost-effectively.

In recent years, there have been several oxygen masks designed specifically for upper endoscopy procedures.<sup>1</sup> These oxygen masks deliver reliably high oxygen concentrations while providing capnography monitoring capabilities and easy endoscopic access.

Capnography and vigilance allow rapid diagnosis of severe hypoventilation, even in a dark room with the patient facing away from us. There are now available endoscopy oxygen facemasks and other devices that make the goal of providing near-maximal preoxygenation prior to the start of deep sedation attainable. These devices may prolong safe apneic time to allow intervention prior to the onset of severe hypoxia.<sup>1</sup>

Improving the safety of the patients we serve requires continual re-assessment of our practices, and a willingness to improve where possible. Since 1955, we have had a simple method, “maximal preoxygenation,” available to prolong safe apneic time.<sup>12</sup> In 2019, there is equipment available enabling us to approximate “maximal pre-oxygenation” prior to induction of hypopnea and insertion of an obstructive endoscope into the upper airway. In his “2019 President’s Report,” Dr. Mark Warner, reiterated the APSF’s vision that “no patient shall be harmed by anesthesia,” and implores us all to continue to work on “this noble quest.”<sup>13</sup>

See “Hypoxia,” Next Page

# Hypoxia During GI Endoscopy

## From “Hypoxia,” Preceding Page

Therefore, our goal should be zero tolerance for hypoxia during upper endoscopies. There is room and opportunity for improvement.

*René Miguel Gonzalez, MD, is a staff anesthesiologist at Hackensack Meridian Southern Ocean Medical Center.*

*The author has no conflicts of interest pertaining to this article.*

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## LETTER TO THE EDITOR:

### Should Medication Labels be Color-Coded?

I read the Pro/Con Debate: Color-Coded Medication Labels in the February 2019 issue of the APSF Newsletter with interest. I found that the companion article “Pro: Color-Coded Medication Labels Improve Patient Safety” provided a reasonable argument for use in clinical practice. However, there are several issues with the Con argument presented. First, Dr. Litman suggests that we should not use color coding because the variety of suppliers do not use the same coding. It would appear that if we accept this notion, we are accepting the present flawed dogma. National organizations may seek ways to urge producers of medications to consider standardizing the colors of their labels. The next reason quoted by Dr. Litman is that those providers that are colorblind will not be able to distinguish label colors. However, for those that are colorblind, it would seem that an emphasis on reading the printed label would be most prudent. This is something we are all expected to do anyway. Another argument proffered is that nurses outside of the operating room may not be familiar with color-coding. However, I see this as an opportunity to educate providers on the value of color-coding medications and standardizing this process throughout hospital care.

Several organizations have expressed concern about color-coding of medication labels. Yet none of them specifically address the high acuity of medication administration in the operating room. Seconds count in giving life-saving medications. Anesthesia professionals are hampered by lighting and patient positioning when administering medications. This work environment is different from anywhere else in patient care. For good reason already, by federal regulation, medical gases must be labeled and color-coded (21 CFR § 201.328).

Organizations such as the Anesthesia Patient Safety Foundation should strongly assert their mission that “no patient shall be harmed by

anesthesia care.” We need to emphasize our work with suppliers of medications and labeling devices to facilitate standardization of medication color labeling. Many industry representatives already ask for our guidance. We need to impress upon our purchasers of medications to only buy compliantly packaged medications, with labels and vial caps complying with the appropriate national guidelines on medication labeling.

*Sincerely,  
H.A. Tillmann Hein, MD*

*Dr. Hein is founder and managing partner of Metropolitan Anesthesia Consultants, LLP, Dallas, TX, and clinical professor of Anesthesiology and Pain Management at The University of Texas Southwestern Medical School. He also serves on the Committee on Quality Management and Departmental Administration for the ASA.*

*Dr. Hein has no conflicts of interest pertaining to this article.*

## RESPONSE:

The purpose of the “Con” perspective was to emphasize the fallibility of reliance on color coding, and to bring awareness to the anesthesiology community that better technological advances (i.e. bar-coding devices) now exist. Although it is not substantiated by epidemiological evidence, it would seem that the combination of colored labels plus confirmatory bar-coding (or another similar technological solution) would be an ideal solution to minimize the incidence of syringe swap. Reliance on an anesthesia professional to prevent errors by always reading the name of the drug on the label each and every time is naive, as human error is not preventable, and arguably normal. We now have the ability to improve upon outdated and unreliable safety systems, and they should be used. The Institute



for Safe Medication Practices (ISMP) has been a proponent of color coding with regard to the American Society for Testing and Materials (ASTM) standard for anesthesia professional applied labels and for outsourced syringes used in the OR. The caveat is that these same color-coded syringes are also not relied upon in other areas of the hospital by non-anesthesia personnel, where same-class syringe mix-ups have occurred. The consequences of an accidental syringe swap error on a hospital ward are likely to be far worse outside the continuously monitored operating room environment. The overarching message of our “Con” approach to color-coding should not be focused on whether or not the color increases or decreases syringe swap, but rather on the need for additional systems-based safety mechanisms (i.e., bar-coding) that provide additional safety to medication administration by anesthesia personnel.

*Sincerely,  
Matt Grissinger, RPh, and Ron Litman, DO*

*Matthew Grissinger RPh, FISMP, FASCP, is director of Error Reporting Programs, Institute for Safe Medication Practices.*

*Dr. Litman, DO, ML, is medical director of the Institute for Safe Medication Practices and professor of Anesthesiology and Pediatrics at the Perelman School of Medicine at the University of Pennsylvania and an attending anesthesiologist at the Children's Hospital of Philadelphia.*

*Neither author has any conflict of interest pertaining to this article.*

*Editor's Note: Our editor's group modified the original title of the article from Matt Grissinger and Ron Litman to reflect the authors' opposition to the reliance of providers on color coded syringes that may provide false reassurance. They do not oppose color coding altogether.*



# RAPID Response Monitoring Gaps

to questions from readers

(Formerly Dear SIRS.) The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the APSF Committee on Technology, is overseeing the column and coordinating the readers' inquiries and the responses from industry. Our editorial board decided to change the name Dear SIRS to *Rapid Response* to reflect the actions the APSF are taking to answer your questions related to technology related safety issues.

## Dear Rapid Response:

The American Society of Anesthesiologists standards for basic anesthetic monitoring require that all patients receiving an anesthetic have arterial blood pressure monitored, at a minimum frequency of once every five minutes, except under extenuating circumstances.<sup>1</sup> Monitoring gaps may occur for various reasons including patient positioning or pausing the automatic cycle for placement of an arterial line. When this occurs, the anesthesia professional sometimes fails to re-engage the monitor to return to periodic measurements, which can lead to extended monitoring gaps. In addition to this human issue, there is a system issue. The design features of some patient monitors, including the General Electric (GE) CARESCAPE B-850, which we use in many of our operating rooms at Michigan Medicine, will display the last measured blood pressure without providing an audible or visual alert if this measurement is not current. This may lead to a false impression that blood pressure is being measured, when in fact the blood pressure displayed is an older measurement. This is in contrast to a detached ECG cable or temperature cable that results in audible alarms. Additionally, a poorly attached cuff or faulty cuff may continue to cycle in an attempt to attain a blood pressure reading without an alert. This can lead to monitoring gaps and potentially compromise patient safety. At Michigan Medicine, we have a system that is designed to integrate with patient monitoring devices and provide alerts for actual and potential issues. This system will alert a provider to a monitoring gap; however, the application needs to be open and running in the operating room and will provide a single beep to alert the anesthesia professional at the six-minute mark if a blood pressure reading is not obtained. It seems as though there should be a simple software solution to this monitoring issue on the GE models that would provide for an alert when a new blood pressure reading is not obtained shortly after five minutes. While this will certainly not eliminate the problem of monitoring gaps, it may help to better identify an issue that can easily be remedied.

Sincerely,  
Sheron McLean, MD

*Dr. McLean is clinical assistant professor in the Department of Anesthesiology at Michigan Medicine, Ann Arbor, MI.*

*Dr. McLean has no conflicts of interest pertaining to this article.*

### REFERENCE

1. American Society of Anesthesiologists. Standards for basic monitoring (1986). <https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring>. Accessed March 2, 2019.

### Reply:

Thank you for highlighting the challenges of non-invasive blood pressure measurements and display within the operating room. When designing a patient monitor, GE Healthcare seeks to support the latest industry standards and trends for delivering care. The design process also includes patient and clinician feedback regarding the reliability and usability of our devices.

The CARESCAPE line of patient monitors, including the CARESCAPE B850 patient monitor, is designed to be used in multiple care areas. GE Healthcare recognizes different care areas utilize the monitor features in different ways, and there can also be different use cases within a single care area. The CARESCAPE monitoring platform has therefore been designed to be flexible, enabling clinicians to configure the monitor to best support the patient needs.

The non-invasive blood pressure (NIBP) display option is one of those flexible features that can be configured to a specific need. As an example, neonatal intensive care unit patients generally do not require frequent NIBP measurements; therefore, CARESCAPE monitor software can be configured for the NIBP measurement to display the last measured value for up to four hours although the value will become "greyed-out" after sixty minutes (Figure 1). In contrast, operating room patients require more frequent NIBP measurements, and for this reason the CARESCAPE software can be configured for the NIBP measurement to automatically cycle

every five minutes (Figure 2), and the measured value will no longer be displayed after 5 minutes (Figure 3).

To turn on automatic NIBP cycling, users can select the NIBP window (Figure 2, Step 1) to open the Non-Invasive Blood Pressure setup window. From the setup window, users may select the appropriate cycle time using the drop-down menu (Figure 2, Step 2); cycle time intervals include minute intervals of 1, 2, 2.5, 3, 4, 5, 10, 15, 20, and 30 and hour intervals of 1, 2, or 4. Once the Cycle Time is selected, users can turn on the NIBP Auto function by selecting Start Cycling (Figure 2, Step 3).



NIBP display with "normal" white text.



NIBP display with "greyed-out" white text.

Figure 1: Example NIBP display text showing color change once the NIBP value becomes aged—e.g., 30 or 60 minutes depending on monitor configuration.

When configuring the monitor defaults, under Care Unit Settings > Parameters, there is an option to select the NIBP Display Timeout duration. Selecting a duration of "5min" (Figure 4) will result in the NIBP value being removed and replaced with dashed lines (Figure 3) five minutes after the last NIBP value is obtained. Other options for the NIBP Display Timeout include 30min/1hr and 60min/4hr and depending on the selection, the last reading will be displayed for one or four hours, with the reading becoming "greyed-out" after either thirty or sixty minutes (Figure 1).

See "Monitoring Gaps," Next Page

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# Monitoring Gaps, cont'd.

## From "Monitoring Gaps," Preceding Page

Another feature to help clinicians recognize when an NIBP reading was last obtained is the numerical display. If the NIBP Cycle Time Display is configured for Numerical display (this configuration is located under Monitor Setup > Care Unit Settings > Parameters), the specific time of the last NIBP measurement is displayed at the bottom right of the NIBP parameter window (Figure 5). This timestamp will be present for both manual and automatic NIBP readings. If the NIBP Auto Cycle is turned on, there will also be a countdown until the next NIBP measurement is scheduled (Figure 5).

If the monitor is attempting to take an NIBP reading, the cuff pressure is displayed on the right side of the parameter window as a visual indicator that a reading is being attempted. If the systolic and diastolic values are removed and the cuff pressure reads "0," this indicates the monitor was unable to obtain a blood pressure measurement. When operating the monitor in the NIBP Auto mode, the monitor will then automatically attempt to capture another NIBP measurement at the next set measurement interval; however, if the underlying condition preventing the capture of the blood pressure persists, the automatic measurement mode will deactivate and the numeric value will remain



Figure 2: "General Electric (GE) CARESCAPE B-850" NIBP automatic cycle configuration.

blank, showing dashes instead of a measurement value. If there is a technical reason for the inability to measure the blood pressure, such as a loose cuff, the monitor will provide an audible alarm along with a message intended to help identify the source of the technical alarm.

Please consult the CARESCAPE monitor's operator's manual or contact GE Healthcare for

additional information on the available setting configurations for blood pressure measurements.

Sincerely,  
Cory Stahl

Cory Stahl is the global marketing manager for GE Healthcare's patient monitoring business, Milwaukee, WI.

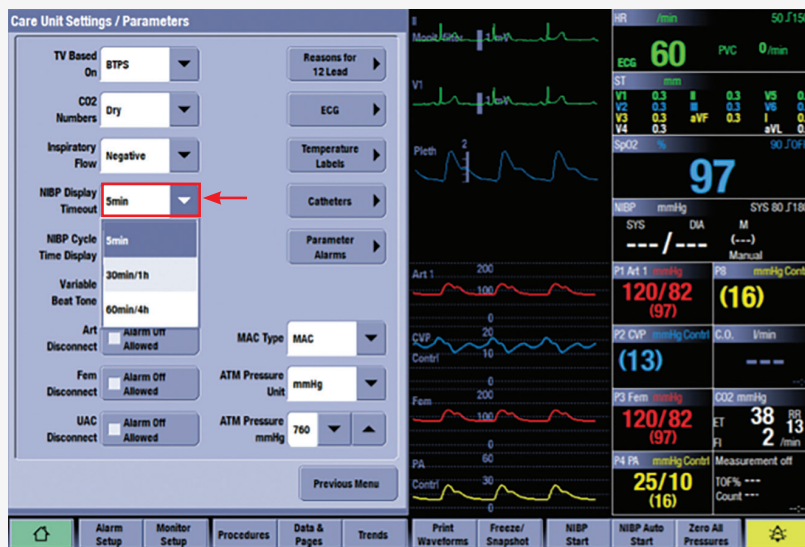


Figure 4: NIBP Display Timeout selection.

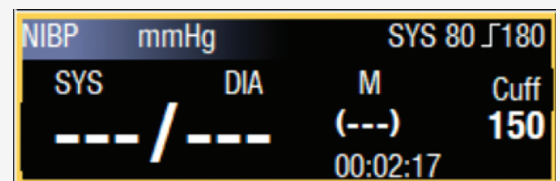


Figure 3: This figure depicts the NIBP display after timeout.



Figure 5: NIBP time stamp and countdown until next cycle.

Time of last NIBP measurement

Time remaining until next scheduled NIBP cycle when in NIBP Auto

### EDITORIAL COMMENTARY:

# The Challenges of Designing Monitoring Displays and Alerts

by Jeffrey Feldman, MD, MSE

In this issue of the *Newsletter*, Dr. Sheron McLean describes a challenge to designing monitoring displays and alerts. Specifically, Dr. McLean identifies the potential for blood pressure monitoring gaps when using a non-invasive blood pressure (NIBP) monitor. The American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring indicate that “Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.”<sup>1</sup> The asterisk refers to the option to alter that interval based upon the discretion of the anesthesia professional as long as the variance is documented in the chart. Current NIBP monitoring devices can be set to cycle at a pre-defined interval, but as Dr. McLean notes, there will be conditions when the measurements are paused intentionally, or the device may be unable to make a measurement. Designing a device that can accommodate these real-world conditions can be a challenge for an engineer. Cory Stahl from GE Healthcare describes the configuration options in their device designed to address these challenges while meeting the needs of different care settings.

One design challenge is how long to continue to display a blood pressure measurement as it ages. The clinician may not observe the measurement as soon as it is completed so it needs to be sustained for some period of time. Should the measured value be removed at the end of the selected measurement interval? What about a single manual measurement? How long should that be displayed? How long is a blood pressure measurement useful, i.e., reflective of the patient’s physiology? To avoid lapses in blood pressure monitoring that extend beyond 5 minutes, the user must respond to any audible alerts or recognize the indications in the display that a measurement has not occurred for five minutes. Those of us in practice know the not uncommon scenario of being absorbed in patient care only to look up at the monitor and realize that more than five minutes have elapsed since the last blood pressure measurement.

Another problem is when and how to alert the user when there is a monitoring lapse. Sup-



pose there is an audible alert every time the device fails to make a measurement. This may be helpful in some circumstances, but undoubtedly will increase the number of nuisance alarms as cuffs are intentionally disconnected or repositioned and measurement attempts are repeated. What should that alert consist of? A gentle audible reminder or a loud alarm? What should the monitor display indicate and will it be noticed? Will the information on the display help the clinician to solve the problem? Clearly there is the potential to add to the problem of nuisance alarms and alarm fatigue without improving the frequency of blood pressure measurement.

One solution described by Dr. McLean to help conform to anesthesia monitoring standards is an independent system that knows the clinical application and the prevailing monitoring standard that can alert the user to a monitoring lapse. This approach adds complexity to the devices needed in the clinical environment in addition to patient monitors, but is likely a viable solution with the use of electronic medical records. These types of alerts have been implemented in a variety of systems at the bedside, but the question remains of how best to alert the clinician to the potential monitoring lapse. Is a visual indicator sufficient? How big is the notice and can it obscure the patient record? Should there be an audible component? If so, how intrusive should it be? In this solution, we still lack any coordination between the elec-

tronic medical record and the monitoring device it is working with.

Dr. Julian Goldman and his colleagues in the *Medical Device “Plug-and-Play” (MD PnP) Interoperability Program* have been advocating an elegant solution for many years.<sup>2</sup> The concept under that program is to have an Integrated Clinical Environment (ICE) where devices communicate with one another. Imagine that when the anesthesia record is initiated, all medical devices connected to the patient are then aware of the context of the care. It will become easier for engineers to coordinate the functions of different devices and to design useful alerts and notifications around compliance with standards and care protocols while minimizing false alarms. Further, the clinician will no longer need to manage multiple devices and understand display options from different manufacturers.

Blood pressure measurement is fundamental to safe anesthesia care. I can recall the time when we used manual blood pressure measurement during anesthesia care and am grateful for the automated devices that undoubtedly provide more frequent blood pressure measurement when caring for patients in the operating room. Modern anesthesia practice benefits from excellent devices to help care for patients. As this discussion highlights, however, there is opportunity for better patient and provider centered designs.

*Dr. Feldman is chair, APSF Committee on Technology, and professor of Clinical Anesthesiology, Children’s Hospital of Philadelphia Perelman School of Medicine, Philadelphia, PA.*

*Dr. Feldman has received consulting compensation from Micropore, Dräger Medical, GE Medical, and Medtronic.*

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# SENSAR, Implementing The Culture of Critical Incidents Reporting Systems

by Alejandro Garrido Sánchez, MD; Rodrigo Molina Mendoza, MD; Eva Romero García, MD; Daniel Arnal Velasco, MD

## INTRODUCTION

A Critical Incident Reporting System (CIRS) collects events or circumstances that may result in unnecessary harm to patients. It is a highly useful tool for the improvement of patient safety (PS), as it prevents avoidable harm by performing a systematic analysis of the latent factors (LF) contributing to adverse events. Several organizations such as the World Health Organization (WHO) and the Agency for Healthcare Research and Quality (AHRQ) recommend the use of CIRS. Their use is founded on the modern principles of a non-punitive, open, fair and learning culture of safety (CS) and require the commitment of individuals and organizations to potentially reduce patient harm in anesthesia practice. National CIRS's have been demonstrated to be essential elements for increasing CS.<sup>1</sup> The most useful CIRS are those which are anonymous and voluntary, focus on learning and employ a national scope. These features facilitate the creation of local solutions to widespread problems through the adoption and execution of improvement measures (IM) designed to prevent critical incidents from recurring.<sup>2,3</sup> A lack of potential reach of existing CIRS's in reducing patient harm as expected by the WHO<sup>4</sup> has been attributed to some known limitations and barriers including a lack of feedback to the professionals reporting incidents, challenges in measuring rates of adverse events, the associated costs of implementation, lack of institutional and economic support, poor implementation, as well as the challenges of analyzing the large volumes of information obtained by the systems. Despite the fact that several initiatives have been launched to increase their use,<sup>5</sup> the potential of CIRS for promoting PS has not been fully realized.

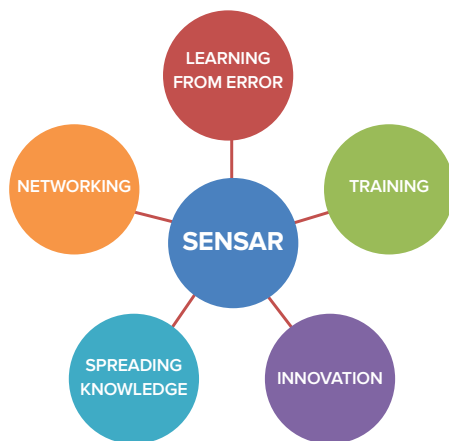


Figure 1: SENSAR multimodal strategy developed in 2013 (5 years after foundation).

**Table 1: Number of Hospitals, Analyzers, Critical Incidents, and Improvement Measures During 10 Years of SENSAR's Experience.**

	Hospitals	Analyzers	Critical Incidents	Improvement Measures
2009	37	183	575	1024
2010	53	246	1438	2570
2011	63	288	2184	3914
2012	69	304	2785	5190
2013	75	335	3568	6470
2014	77	351	4714	8662
2015	78	356	5993	10930
2016	90	425	7170	13256
2017	101	484	8352	15596
2018	107	518	9392	17722

The Spanish Anesthesia and Recovery Safety Notification System (SENSAR, by its Spanish acronym) is a CIRS created in 2009 with the participation of 16 hospitals throughout Spain. It evolved from a single center system implemented in 1999 within the Hospital Universitario Fundación Alcorcón. Five years later the CIRS was enhanced with a multimodal strategy (MMS) to improve its performance in critical incident reporting, analysis and the execution of derived IM (Figure 1). After ten years of experience, SENSAR has expanded to include 107 hospitals (100 in Spain, 7 in Chile), consisting of more than 500 analyzers, who have examined 9,274 reports of critical incidents and implemented 17,056 improvement measures (Table 1). Over time, what started as a single center CIRS, has been transformed into an organization that serves as a model for improving peri-operative patient safety throughout Spain, Europe, and Latin America.

## AN OVERVIEW OF OUR CIRS

SENSAR's CIRS is a non-punitive, anonymous and confidential learning tool that provides agility in the management of the information received, by providing immediate feedback in the form of actionable IMs. It also promotes data sharing at a national level, as it is managed by groups of local PS experts who share their data and educational projects through professional networks and communities.

Patient safety is an essential measure of quality of care and risk management. In recent years, we have directed efforts toward developing and measuring the CS throughout our organizations, which thereby allows a wider

range of action, resulting in a greater impact derived from the IMs employed. This cultural change involves a process of collective learning that focuses on the system, and not on the individual. It is based on understanding the causes of CIs in order to adopt measures that will be able to prevent them. Reason's model of human error, which is widely accepted, serves as a foundation for the system.<sup>6</sup> This model acknowledges that human beings are fallible and that mistakes made by individuals are therefore expected. However, these human errors must be seen as consequences and not as causes, since they originate from factors within the health care system. Therefore, individuals not only have to avoid making errors, but, in addition, the health care systems should have protective measures in place to prevent them. Employing this approach, each CI is a learning opportunity to identify and correct the contributing factors, and not a situation to blame the individual involved in making the error. The following four cultural elements are important for achieving a PS culture: 1) *Communication*, in which health care providers perceive a nonpunitive atmosphere, which encourages the reporting of CIs and allows them to speak freely about them with others; 2) *Justice*, in which unacceptable and dangerous behavior is clearly differentiated from behavior that, although erroneous, is understandable or explainable; 3) *Flexibility*, which allows changes in the hierarchical structure to adapt to risk situations; and 4) *Learning*, with the desire to gain insight from the analysis of CIs and the willingness to implement necessary modifications.<sup>7</sup>

See "Critical Incidents Reporting Systems,"  
Next Page

# Critical Incident Reporting Systems Aid In Developing Improvement Measures

From “Critical Incidents Reporting Systems,”  
Preceding Page

## OUR APPROACH

SENSOR's approach focuses on analyzing CIs using a framework to identify the associated latent factors, among which we consider: 1) the individual (anesthesia professional or other health care provider) in direct contact with the patient; 2) the team of professionals involved with the CIs, as well as the communication between them; 3) the task(s) being performed; 4) the patient, which includes his or her clinical condition; 5) the workplace; and 6) the organization. SENSOR facilitates learning from errors systematically, and thereby helps to promote safety in the health care environment, by providing a vehicle by which to analyze incidents without damage to the patient. We believe that studying and controlling latent factors is not only key to performance improvement, but also the most effective way to prevent CIs from reoccurring.

The reporting of CIs within SENSOR's 107 member hospital collaborative occurs through an electronic form with generic access codes, unique for each center (Figure 2). Our system uses an online platform, called PITELO (an acronym for the most common latent factors **P**atient–**I**ndividual–**T**ask–**i**Team–**p**Lace–**O**rganization), which is accessed through its website ([www.sensor.org](http://www.sensor.org)). The communication form is structured to facilitate the introduction of the data and avoid the loss of relevant information. (Between 2009 and April 2017 SENSOR's CIRS was known as ANESTIC.)

The CIs of each hospital reported in SENSOR's database are available to the local analysis group. This analysis group is composed of a minimum of three to a maximum of six anesthesia professionals; and usually includes the head or chief of staff, as a way to facilitate and expedite the implementation of IMs if needed. Each member of the analysis group assumes responsibility for the CIs reported during a designated period of time (weekly or monthly depending on the volume of communications) and acts as the “speaker” for the rest of the group. His or her function includes the comprehensive review of each incident during the assigned interval, erasure of all identifying information contained that would prevent anonymity (proper names, dates, clinical history numbers, etc.), review of the hospital's individual database for similar CIs (as well as the database from other hospitals contributing to SENSOR if available). The analysis performed is focused on the system to determine the latent factors contributing to the occurrence of the CI, and results in the proposal of corrective measures that address each of the latent factors identified.



Figure 2: SENSOR's login to PITELO, its online communication and analysis platform.

## OUR RESULTS AFTER TEN YEARS

SENSOR has grown from its original sixteen members, to a network of 100 hospitals in Spain, and 7 hospitals in Chile. It contains more than 9,000 incidents in its database, and includes almost twice as many proposed IMs for preventing future adverse events. Despite this success, greater efforts are needed in order to keep up with the current implementation and allow for further growth. Among the biggest challenges in ongoing efforts is motivating health care providers to report CIs.

Regarding the nature of the CIs reported to the SENSOR database, clinical errors were the most common incidents reported (25%), followed by medication errors (21%) and equipment malfunction (20%). Fortunately, less than five percent of the incidents reported in our database posed a lethal threat to the patient involved. Importantly, SENSOR, allows us to learn from and develop useful IMs from incidents posing low, intermediate, or high risk to patients. Measures derived from our analysis have varied in complexity. The majority of the IMs in our database tend to be educational or informative, i.e., alerts, communications, clinical sessions, or debriefings, for staff members designed to help providers avoid factors that lead to the CI; 1,568 clinical protocols have been created or modified among our 107 member hospitals as a result of the analysis. In order to make our system sustainable and as part of our “Spreading the knowledge” MMS, we have been able to implement PS courses focused on CIRS at a local, national, and international scale (Chile); training more than 450 professionals in Spain and over 180 in Chile.

We believe the anesthesia professional is evolving towards a safer practitioner by following this system. The impact of the developed MMS utilized by SENSOR has resulted in a meaningful advancement in the field of anesthesia PS and related areas, enhancing the CS of professionals and institutions. SENSOR might serve as a model for enhancing patient safety more globally.

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*The authors have no conflict of interest pertaining to this article. SENSOR is a non-profit and public advantage organization.*

NOTE: Tables and figures are original from SENSOR.

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LETTER TO THE EDITOR:

# Double-Lumen-Endotracheal/Endobronchial Tube Diameter Size Indicators on Packaging Remain Suboptimal

Over two decades ago several publications warned anesthesia professionals that traditional formulas and estimations are inadequate to allow for an individualized and appropriate choice of Double-Lumen-Endotracheal/Endobronchial Tube (DLT) size for a given patient.<sup>1,2</sup>

In a letter to the editor, Dr. Slinger made the important observation that “when we cannot reliably predict a clinically important variable, then we need to measure it.”<sup>3</sup> Furthermore, the letter states that “Tubes should be clearly labeled with their maximum tracheal and bronchial diameters so that we can choose the correct tube.”<sup>3</sup>

We queried our Cardiothoracic Anesthesiology staff and found that the majority use computed tomographic (CT) chest scan images to assist in choosing an individualized and appropriate DLT. This approach agrees with the statement by Hannallah et al. that “CT scan measurement of left bronchial diameter can objectively guide the choice of left DLT size for an individual patient.”<sup>2</sup> This would satisfy the first call for action for a more evidence-based patient-centered DLT choice.

The second call for action and current weak link in our system is how to compare the measurements obtained on CT imaging to the measurements seen on DLT packaging. One can obtain the endotracheal but not the endobronchial size from current packaging and package insert (Figure 1). To solve this dilemma, our staff



Figure 1: Examples of endobronchial diameters not indicated on Shiley or Mallinckrodt (Covidien, Mansfield, MA) DLT packaging.

often refer to size tables from previous publications,<sup>1,2</sup> although data from these publications note manufacturer variability in diameter sizes. We are not aware of a standardized process for manufacturing or labeling DLTs. For example, a specific sized DLT from one manufacturer may have a different outer endobronchial diameter compared to the same sized DLT from another manufacturer. Figure 2 demonstrates a simple technique for determining endobronchial tube diameter. We measured the Shiley (Covidien, Mansfield, MA) DLT with precision calipers and found that the outer endobronchial measurements differed from other manufacturers’ based on previous publications provided by Mallinckrodt (Table 1).<sup>1,2</sup>



Figure 2: Example of a Shiley 37 Fr Left DLT endobronchial measurement (in mm, this important endo-bronchial diameter is not indicated on the packaging, see Fig. 1).

**Table 1: Outer tube diameter measurements of available DLTs (Shiley and Mallinckrodt) from our facility**

DLT Size (avail. for measurement)	Endotracheal Diameter (mm)	Endobronchial Diameter (mm)
35 Fr Left (3)	11.92	9.56
	12.29	9.48
	11.84	9.59
Average	12.02	9.54
37 Fr Left (4)	12.31	9.87
	12.80	9.90
	12.52	9.93
	12.87	9.97
Average	12.63	9.92
39 Fr Left (4)	13.26	10.30
	13.04	10.16
	13.21	10.08
	13.37	10.25
Average	13.22	10.20
41 Fr Left (2)	13.45	10.87
	13.73	10.74
Average	13.59	10.81

We are already one step closer to minimizing iatrogenic bronchial DLT injury to our patients by measuring main bronchial diameters on CT as suggested by Hannallah et al.<sup>2</sup> To now find the optimal DLT, we need the second piece of information. We believe the outer endobronchial diameter should also be clearly indicated on the package, and not merely the endotracheal diameter. This would then satisfy both requirements for an optimal patient-DLT-match. This would seem to be an easy improvement process, as it only requires the manufacturer to add the product specification “bronchial diameter” to the package for clinicians’ perusal.

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*The authors have no conflicts of interest pertaining to this article.*

*Editor’s Note: We have reached out to a variety of companies to address this issue and an article will be forthcoming in a future APSF Newsletter issue. Several vendors who manufacture double lumen endotracheal tubes have been contacted by APSF and are investigating the possibility of adding bronchial lumen size labeling to the product packaging.*

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## A Tale of the Wet Anesthesia Machine

### Q Dear Q&A,

A recent event in our operating room has led me to inquire about the suitability and/or safety of using an anesthesia machine that has been saturated with water due to a ceiling sprinkler activation. A sprinkler head in one of our operating rooms was inadvertently activated. The anesthesia machine (Dräger Apollo-2012, Telford, PA) was directly below the sprinkler, and as a result, was saturated with water (Figures 1 & 2). After the machine had dried, the inspector tested the machine, and it has been deemed clear to use. I am told no infection control tests were performed, only a test of machine functionality.

The affected machine was removed from service at the time of the event and has remained out of service. My question is whether this machine is safe for patient use from an infection control perspective moving forward. There was standing water in and on this machine during the sprinkler activation. Are there other standards or tests we should be adhering to before putting this machine back into service?

*Thank you for your time,  
Brooke L. Williams, MNA, CRNA, APNP*

*Milo C. Huempfer VA Clinic  
Green Bay, WI*

*This author has no conflicts of interest to report.*

### A Dear Ms. Williams,

Dräger would like to thank the Anesthesia Patient Safety Foundation (APSF) for the opportunity to respond to the above submission.

The author describes a situation where an Apollo anesthesia machine was beneath an operating room sprinkler head, and the sprinkler was inadvertently activated resulting in an Apollo anesthesia machine saturated with water. The author is asking if the Apollo can be put back into service, and if so, are there any concerns from an infection control standpoint. The Apollo anesthesia machine Instructions For



*Figure 1: This figure shows the extent of water on the floor (which is not black, but appears black due to the water and residue).*



*Figure 2: This figure depicts the water pouring down over the top of the machine after spraying out of the sprinkler system above.*

Use (IFU) specifications state that the Apollo must be stored in an environment of 25% to 85% relative humidity (no condensation). In the case of the activated sprinkler head, this specification was violated. Although the author states that the machine checked out functionally, Dräger cannot guarantee there is not internal contamination or other related conditions resulting from the exposure to water that could lead to future device malfunction. Corrosion and/or mold/mildew may also be a future concern. It is Dräger's recommendation that the machine should not be used until the potential internal contamination and/or latent damage is assessed and resolved, if possible, by an expert

in this field. This type of assessment is beyond the expertise of Dräger. If this type of assessment is not possible, it is Dräger's recommendation that the machine be replaced and not be put back into use.

In summary, Dräger would like to thank the authors for sharing this unique scenario with the anesthesia community.

*Thank you,*

*David Karchner*

*David Karchner is senior director of Marketing, Operating Room, Service, and Government Solutions at Dräger Medical.*

**See "Wet Machine," Next Page**

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



## Editorial Commentary: Wet Machine

From “Wet Machine,” Preceding Page

Dear Ms. Williams,

The *APSF Newsletter* receives interesting letters that often challenge our knowledge and expertise.

Water saturation of an anesthesia machine from a ceiling sprinkler activation is an exceedingly rare event, and it is difficult to provide a response that is well supported by data or past experience. The response from Dräger Medical, the manufacturer, is very useful as it underscores the challenge to finding truly expert advice on the best course of action. This experience raises the more general question about the role of the anesthesia professional in assessing the safety of equipment to be used for patient care.

Ms. Williams is to be commended for questioning the safety of this anesthesia machine after such significant water exposure. Although the hospital biomedical technicians can be helpful in this situation, the ultimate responsibility lies with the anesthesia professional to be as certain as possible that equipment is safe before beginning an anesthetic. One can imag-

ine the pressure on a hospital administrator to keep this expensive device in clinical use maintaining continued use of the operating room and avoiding the cost of replacement. The anesthesia professional is uniquely qualified to raise concerns about the safety of the equipment that administration may not appreciate.

The report mentions that an “inspector” deemed the machine clear to use. It is not clear from this report how the inspector was qualified to render an opinion. Technicians are not required to be manufacturer certified to provide service to anesthesia machines and many are not. Even technicians who are manufacturer certified can be independent contractors and may not have access to the manufacturer for an opinion. In this case, an official opinion from the manufacturer is warranted and although it may not be the desired opinion, it does clarify the potential liability of continuing to use the machine.

Even though an inspector indicated the machine is clear to use, given the information from the manufacturer, it is not clear who might be able to provide a sufficient expert opinion to

warrant continued use of the device. If the machine did stay in service and resulted in patient injury, not only would the caregivers be burdened by their sense of responsibility for the patient’s injury, but the liability could be difficult to defend.

Practicing with a questioning attitude is a core patient safety principle. Whenever there is a concern about the safety of medical devices for patient care, the anesthesia professional should not begin an anesthetic until the concern has been addressed. If an inspection is performed, the qualifications of the certifying inspector should be documented, and, if necessary, an opinion from the manufacturer should be sought.

*Dr. Feldman is chair, APSF Committee on Technology, and professor of Clinical Anesthesiology, Children’s Hospital of Philadelphia Perelman School of Medicine, Philadelphia, PA.*

*Dr. Feldman has received consulting compensation from Micropore, Dräger Medical, GE Medical, and Medtronic.*

## RAPID Response

to questions from readers

## Humidity Levels in ORs

### Dear Rapid Response:

At our institution, we recently encountered an issue with our HVAC system that left the operating room humidity at approximately 70%. Our operating rooms were closed because of this, and no cases were done while we were out of compliance. A joint statement published by multiple societies in 2015 recommends a relative humidity of 20%-60%.<sup>1-7</sup> My question has two parts: (1) how was the upper limit of 60% decided, and (2) what are the real-life dangers of delivering an anesthetic and performing an operation in a setting with a humidity greater than 60% or less than 20%?

*Thank you again for your time.*

*De-An Zhang, MD*

*Physician Director of Perioperative Services  
Shriners For Children Medical Center  
Pasadena, CA*

*Dr. Zhang reports no conflicts of interest.*

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### Reply:

The short answer is that a short-term increase in relative humidity (RH) above the limit of 60% has little impact on the safety of anesthesia care. In the long term, it may affect operating room and instrument sterility.

The current standard on operating room RH levels is set to be between 20% and 60% by the American Society of Heating, Refrigeration, and Air Conditioning (ASHRAE).<sup>1</sup> Other standards writing organizations, such as the National Fire Protection Association and the Facility Guidelines Institute, refer to this standard.<sup>2,3</sup> Both the Centers for Medicare & Medicaid Services (CMS) and the Joint Commission enforce these limits and require continuous monitoring of operating room temperature and humidity to insure they are in constant compliance when being used for their intended purpose; inspectors typically accept temporary deviations that are resolved within 24 hours.

See “Humidity,” Next Page

## Humidity Levels in ORs, cont'd.

### From "Humidity," Preceding Page

The instruction for use of some supplies and equipment have even tighter RH limits for storage and/or use; and the facility should also monitor that the operating rooms and storage areas are within these limits. Justifiably, your institution chose not to do cases in operating locations that are outside of the recommended humidity limits.

### The rationale for the current 20% lower limit is that Low RH:

- decreases the shelf life of certain supplies, such as biological indicators and chemical indicators used for sterilization monitoring, and electrocardiogram electrodes.
- increases the chance of electrostatic discharge that could harm or interfere with electromedical equipment,<sup>4</sup> and potentially spark a fire (this is less of a recent issue because the risk of electrostatic discharge is less with nonflammable anesthetics and antistatic surgical gowns).

### The rationale for the current 60% upper limit is that High RH:

- increases the chance of surface mold and mildew growth;
- may increase the risk of wound infections;
- is less comfortable for operating room personnel.

It should be noted that there is sparse experimental evidence documenting the exact levels where these risks increase.<sup>5-6</sup> In 2008 the limits were relaxed because the HVAC equipment and fuel costs to meet the previously standardized limits of 35% to 60% were felt to be unnecessarily costly. There remains debate about the safety of the relaxed range (20-60%). A recent review of 10 years of reports to the FDA MAUDE database on electrostatic discharge by medical devices identified low RH (< 30%) as a contributing factor in some of these events.<sup>4</sup> The authors also highlighted that instructions for use (IFUs) for most electronic devices recommend a minimum RH of 30%. Furthermore, CMS mandates conformance with the IFU recommendations.<sup>4</sup> ASHRAE has yet to revise the standard to be consistent with the manufacturer recommendations.

Relative humidity is the amount of water vapor present in air expressed as a percentage of the amount needed for saturation at the same temperature. RH depends on the temperature and pressure of the system of interest. To acutely decrease the RH level of an

### Humidity and Temperature from a single OR over 2-months

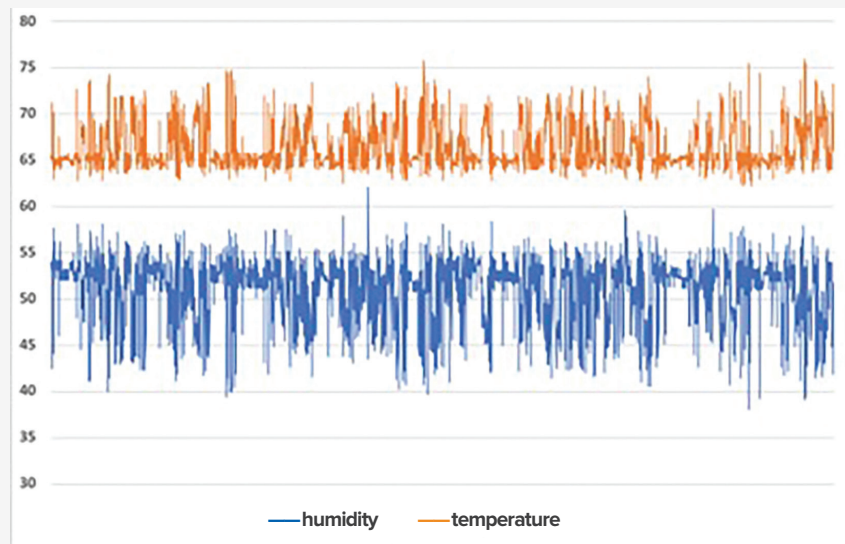


Figure 1: Humidity and temperature from a single OR over 2-months. Note the inverse relationship between temperature and relative humidity.

operating room, one can either remove water vapor or increase temperature (it is unlikely that one would increase the atmospheric pressure). Cold operating rooms have a higher RH than do warm operating rooms with the same absolute humidity (Figure 1).

It is not uncommon for the OR environment to periodically exceed approved limits depending on geography and the type of cases. Northern and western climates often experience low RH, especially in the winter months, and have difficulty raising the RH to the lower limits. Conversely, hospitals in southern and coastal areas experience high ambient RH and systems are designed to remove humidity from the fresh air. While an OR operating at 70 degrees and 50% RH is well within standards, dropping the temperature to 60 degrees for case requirements or staff comfort would cause the RH to exceed the limit.

Whenever the RH of a room extends beyond the approved limits, a risk assessment (RA) of the event should be conducted to insure there is no adverse effect.<sup>6</sup> A multidisciplinary group including physicians, surgical staff, Infection Control, OR management, Clinical Engineering, Supply Chain, and Facilities Engineering personnel should participate in the RA. A review of the event, and its impact on environmental or operational conditions should be evaluated and documented. The RA becomes the evidence that the operational breach had no negative safety consequence, and may also be used as a basis for future performance evaluations. This

RA documentation also serves as a record of performance when authorities having jurisdiction perform inspections.

*Robert G. Loeb, MD, is professor of Anesthesiology, University of Florida, Gainesville, FL.*

*Dr. Loeb serves as chair of the American Society of Anesthesiologists Committee on Equipment and Facilities. He is on the technical advisory committee of, and has been an invited speaker for, Masimo, Inc.*

*Bradley S. Pollitt, AIA  
Vice President, Facilities  
UF Health Shands Hospital, Gainesville*

*The authors have no conflicts of interest pertaining to this article.*

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# Acute Citrate Toxicity Linked to Excess Citrate-Phosphate-Dextrose Solution in Autologous Blood Transfusion

by Brian Butala, DO; Marc Rodrigue, DO; Joshua Baisden, MD



## INTRODUCTION

Autologous blood transfusion used in cardiac surgery aims to minimize allogeneic blood transfusion, which is costly and associated with complications. Autologous blood is generally drawn into bags containing heparin or citrate-phosphate-dextrose (CPD) solution to minimize coagulation during storage. After cardiopulmonary bypass (CPB) and protamine administration, autologous blood is returned to the patient as whole blood. We present a case of intraoperative acute and severe citrate toxicity secondary to autologous blood transfusion after aortic valve replacement (AVR) and the development of an institutional protocol for autologous blood transfusion to prevent similar toxicity.

## CASE PRESENTATION

A 76-year-old female presented for AVR. Her past cardiac history included severe aortic stenosis and non-obstructive coronary artery disease. Induction and intraoperative course, including bypass separation, were uneventful. The patient's initial post CPB transesophageal echocardiogram (TEE) was unremarkable, heparin was reversed with protamine, and autologous blood was infused centrally during operative closure. After half of the autologous blood was administered, acute and severe hypotension was noted; pulmonary artery pressures were consistent with baseline and a TEE showed normal biventricular function. This shock was treated with volume expansion and phenylephrine. The hypotension worsened and a subsequent TEE revealed cardiac standstill requiring CPR and reinstitution of CPB. Multiple doses of epinephrine, vasopressin, and later calcium were given with little effect.

Differential diagnosis included citrate toxicity, coronary air embolism, coronary occlusion, pulmonary embolism, prosthesis failure, protamine reaction, or other drug reaction. An ABG drawn during decompensation was remarkable for a mild acidosis, mild anemia, and an ionized calcium concentration of 0.25 mmol/l (reference normal 1.07-1.25 mmol/l). The patient's calcium

**Table 1: Protocol for Autologous Blood Transfusion**

- Blood drawn after central line insertion into pre-prepared CPD containing bags in approximately 400 mL aliquots
- < 300 ml volumes prompt discussion of safety for transfusion
- Blood placed on agitator to limit stasis and thrombus formation
- After protamine administration, autologous blood transfused over 10 minutes through a fluid warmer with a filter

prior to CPB was normal. Acute citrate toxicity was the presumed diagnosis as the others in our differential would not cause acute and severe hypocalcemia. The patient's calcium was replenished and allogeneic blood was transfused. The patient was successfully weaned from CPB again with minimal support, extubated on post-operative day (POD) #0, and discharged POD #5 without issues.

## DISCUSSION

Acute citrate toxicity causing hypocalcemia can occur following autologous blood administration containing CPD solution. Excessive citrate concentrations lead to chelation of calcium ions, resulting in severe decreases in ionized calcium fractions. Our practice of placing CPD into autologous units was not standardized previously, and, therefore, a significant dose of CPD in the unit could have caused this phenomenon in this case. Signs and symptoms of citrate intoxication can include arrhythmias, narrow pulse pressure, severe hypotension, increased end diastolic pressure, and increased central venous pressure. Under normal physiologic parameters, transfusing blood at a rate of more than 1 unit per 10-minute period is required for a reduction in blood calcium levels.<sup>3</sup> However, conditions that decrease citrate metabolism (hypothermia, liver transplantation, liver disease) or decrease serum ionized calcium (hyperventilation, alkalemia) may decrease this threshold.<sup>3</sup> However, we believe

that rapid transfusion of high concentration CPD blood is implicated in our case.

Following this case, a multidisciplinary discussion resulted in standardization of our autologous blood transfusion protocol (Table 1). We now use standardized CPD containing bags, a filter attachment on blood administration tubing, as well as an agitator to limit stasis of donated blood. Since institution of this protocol, we have not experienced acute citrate toxicity associated with autologous blood transfusion.

*Dr. Butala, is a fellow in Adult Cardiothoracic Anesthesiology in the Allegheny Health Network, Pittsburgh, PA.*

*Dr. Rodrigue is a resident in Anesthesiology in the Allegheny Health Network, Pittsburgh, PA.*

*Dr. Baisden is systemwide director of Cardiothoracic Anesthesiology in the Allegheny Health Network, Pittsburgh, PA.*

*The authors have no conflicts of interest pertaining to this article.*

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## 2019 APSF Trainee Quality Improvement (TQI) Recognition Program

**The project submission deadline:  
August 16, 2019 at 11:59 pm**

The APSF Committee on Education and Training announces the fourth annual APSF Trainee Quality Improvement Program. The 2019 program will again host tracks for resident physician anesthesiologists, student registered nurse anesthetists, and anesthesiologist assistant graduate students. The APSF invites all US and Canadian anesthesia professionals in

training to demonstrate their program's work in patient safety and QI initiatives. The APSF will accept up to two completed submissions from each US and Canadian training program in each specialty track.

More information and details on the submission process are listed on the APSF website (<https://www.apsf.org>). Additionally, please email any inquiries to [residentqi@apsf.org](mailto:residentqi@apsf.org). The top two projects in each track will

receive APSF recognition and financial rewards of \$1,000 and \$500, respectively. Resident Physician and Anesthesiologist Assistant Graduate Student winners will be announced at the 2019 Annual Meeting of the American Society of Anesthesiologists and Student Registered Nurse Anesthetist winners will be announced at the 2019 American Association of Nurse Anesthetists Annual Congress.

# RAPID Response

to questions from readers

## Lightwand-Guided Intubation: How Long is the Stylet?

### Dear Rapid Response:

Lighted stylets are an important component of the ASA Difficult Airway Algorithm.<sup>1</sup> Particularly useful in patients with blood or secretions in the airway, lightwands are also helpful in scenarios involving unstable cervical spines and limited mouth openings. During an otherwise routine lightwand-guided endotracheal intubation, we encountered difficulty placing the bulb of the lightwand at the tip of the endotracheal tube (ETT) because the length of the stylet was short. Below, we describe both variation and inadequacy in the length of the available Vital Signs<sup>®</sup> Orotracheal Lighted Stylets (Vyair Medical, Mettawa, IL) at our institution.

The product packaging indicates that the stylet can be paired with ETT sizes ranging from 6.0 mm to 10.0 mm without specifying ETT brand.<sup>2</sup> However, increasing ETT diameter corresponds with increased ETT length. In our case, a 7.5 mm ETT was used and the tip of the lighted stylet was unable to reach the ETT tip, leading to inadequate transillumination and multiple intubation attempts. We then compared the lengths of different Vital Signs<sup>®</sup> Orotracheal Lighted Stylets in our inventory and noticed a variation in the length of the stylets (Figure 1).

We then compared the lengths of available stylets for use with ETTs 7.5 mm and greater and found that the stylets fell significantly short of the desired length (Figure 2).

Based on these observations, we recommend checking the length of Vital Signs<sup>®</sup> Orotracheal Lighted Stylets in relation to the desired ETT size to potentially improve first attempt success of intubation, and subsequent patient safety. Given the lengths of available Vital Signs<sup>®</sup> Orotracheal Lighted Stylets, we found 7.0 mm to be the maximum recommended ETT size that can be used reliably.

*Dr. McCormick is a CA-2 resident and Dr. Maheshwari is an assistant professor in the Department of Anesthesiology at the University of Oklahoma Health Sciences Center.*

*The authors have no conflicts of interest pertaining to this article.*

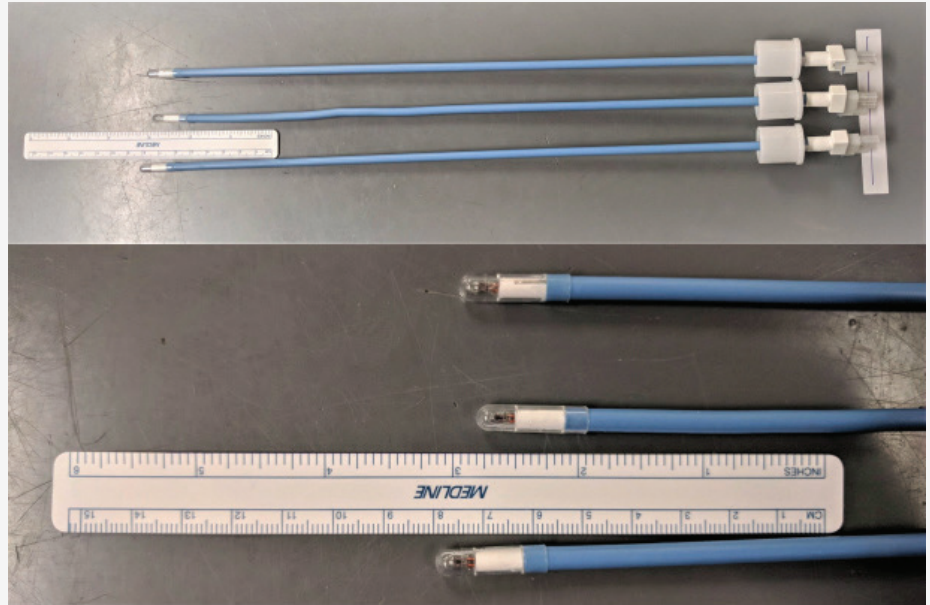


Figure 1: Example of three identically packaged Vital Signs<sup>®</sup> Orotracheal Lighted Stylets (CareFusion). The variation in length approaches one centimeter.

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### Reply:

Product quality is of vital importance to Vyair, as is customer service. We have taken this observation and communicated to both our quality team and customer service teams for further review. We'd like to let the readers know that an in-depth review of the product design is to occur taking into consideration the information supported by this letter. We thank the APSF and Drs. McCormick and Maheshwari for always thinking of the patient first, as we all do, and alerting us to potential opportunities to improve patient care via our products.

*Sincerely,  
Steven H. Cataldo, MD  
Vice President & Medical Director  
Vyair Medical  
Mettawa, IL*



Figure 2: Size 8.5 mm endotracheal tube with the Vital Signs<sup>®</sup> Orotracheal Lighted Stylets (CareFusion) and light turned on and off. The lighted stylet falls approximately 2-3 cm short of the length required for appropriate positioning at the endotracheal tube tip.

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# APSF Trainee Quality Improvement (TQI) Recognition Program Update: Lauren Easterbrook, APRN, CRNA, DNAP

Lauren Easterbrook, RN, BSN, from the Mayo Clinic Nurse Anesthesia Program recently was recognized by the APSF for her work on patient safety involving the creation of a video entitled "Improving Medication Handoff Practices Between Post Anesthesia Care Unit (PACU) Nurses and Anesthesia Providers."

## Question 1: What inspired you to undertake your project?

We can provide the best anesthesia in the world, but if there are breakdowns in communication across the perioperative period, then we have done a disservice to our patients. Anesthesia handoffs were a highlighted area where I could help improve patient care. The PACU nursing staff, anesthesia providers, and my doctoral project mentors were incredible to work with and champions for patient safety. I was inspired by each individual team's desire to improve patient care and work collaboratively to do so. Nursing research practices focused on observation, patient centered care, and holistic health were what really helped me to create a project that was impactful for our patients and staff.

## Question 2: What are your future plans for this work?

Modes of communication and information sharing change as health care technology

evolves, and it is always evolving, forcing us to constantly evaluate the mistakes we make in handoff communications. I want to continue to work with nurses, APRNs, and physicians, to create projects that help improve patient care. We have formed a Handoff Task Force with people from all disciplines to create a safe handoff process across the Mayo enterprise.

## Question 3: What are your future professional plans?

I intend to keep learning and seeking new opportunities for ways that we can improve our anesthesia practice. I would love the chance to work with multidisciplinary teams in perioperative medicine at Mayo Clinic and around the country.

My goal is to work with students in the Mayo Clinic Doctorate of Nurse Anesthesia Practice Program as they work on their own doctoral projects. It's exciting to see the unique and impactful contributions these students are making to anesthesia research.

## Question 4: Please share one good thing about the APSF Trainee Quality Improvement Program.

My favorite part about the APSF TQI Program was meeting the APSF board at the Boston AANA conference. I have met such inspiring anesthesia



professionals through the TQI program, including Maria Van Pelt and Arnoley Abcejo, and hope to continue to collaborate with the APSF organization in future research projects.

Lauren Easterbrook is a doctorate student of Nurse Anesthesia Practice at the Mayo Clinic School of Health Sciences Nurse Anesthesia Program in Rochester, Minnesota.

Lauren Easterbrook has no conflict of interest pertaining to this article.

## Anesthesia Professionals Should Continue to Develop Safe Practices and Guidelines for NORA

From "NORA," Page 4

Anesthesia professionals need to continue to define safe practices, establish appropriate guidelines, direct efficient resource management and establish risk related data. A continued emphasis must be placed on the education of our specialty through NORA specific trainee education and lifelong learning. As we look to provide efficient and safe NORA, we need to continue to evolve, utilizing advances in technology to improve our ability to preoperatively assess patients, monitor patients during and after procedures, and provide targeted anesthetics for a multitude of increasingly complex cases.<sup>9</sup>

### CONCLUSION

NORA is an emerging field that is at the forefront of increasing the availability of procedural care for a wider variety of patients. Utilizing new technology to treat a wide variety of patient ailments will continue to lead to new challenges for the anesthesia professional providing NORA. Better understanding of safe practice and the risks associated with NORA will allow anesthesia professionals to be at the frontline

of this rapidly evolving and expanding sub-specialty.

*Dr. Walls is assistant professor of Clinical Anesthesiology and Critical Care at the University of Pennsylvania School of Medicine.*

*Dr. Weiss is assistant professor of Clinical Anesthesiology and Critical Care at the University of Pennsylvania School of Medicine.*

*The authors have no conflicts of interest pertaining to this article.*

*The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of APSF. It is not the intention of APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.*

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# ERAS: Roadmap For A Safe Perioperative Journey

by Rebecca N. Blumenthal, MD

## INTRODUCTION

An opioid epidemic has spread across the United States as a result of the misuse, abuse, and diversion of prescribed opioid medications. Chronic opioid usage often begins with a prescription for opioids given for acute pain to a postoperative patient. Alarming, up to 10% of opioid naïve post-surgical patients become chronic opioid users.<sup>1</sup> Even short courses of opioids can have long term consequences, and patients leaving the hospital with a prescription for opioids have an increased likelihood for long term opioid use.<sup>2,3</sup> Research suggests that patients who have a high requirement for opioids as an inpatient typically utilize large quantities of opioids after discharge as well.<sup>2,4</sup> This national opioid crisis has left hospitals, clinicians, and health systems across the United States with the responsibility of finding solutions, particularly alternatives to opioid administration for perioperative pain management.

Enhanced Recovery After Surgery (ERAS) protocols provide transformative plans for minimizing pain, reducing opioid administration, expediting patient recovery, and decreasing perioperative complications and hospital length of stay.<sup>5</sup> ERAS care maps are evidence-based, multidisciplinary, and collaborative approaches to perioperative care based on scientific principles that optimize preoperative, intraoperative, and postoperative care. ERAS pathways are clinical care bundles that provide consistent approaches to perioperative care. Most importantly, in addition to improving patient outcomes, ERAS care maps and standardization have resulted in dramatic declines in opioid usage in surgical patients.

The concept of ERAS was developed in Denmark in the late 1990s by colorectal surgeon Dr. Henrik Kehlet. Dr. Kehlet suggested that by combining multiple scientifically validated perioperative interventions (thoracic epidurals, early nutrition, and early ambulation) into a synergistic package, ERAS protocols could lead to significant improvements in patient recovery and safety.<sup>6</sup> In a recent editorial, Dr. Kehlet and colleagues emphasized the importance of evidence-based support for all ERAS interventions. They stated that the failure to apply rigorous science and pathophysiologic principles in the expansion of ERAS to various surgical subspecialties, might threaten the future success of ERAS.<sup>7</sup> With this concept in mind, it is important that each hospital designs institution specific evidence-based ERAS protocols. Creation and rollout of ERAS protocols is a difficult and time-consuming project that presents

many challenges for hospital systems. There are a number of limitations and roadblocks that may impede successful ERAS implementation including cost restraints, resource availability, time, administrative support, a lack of enthusiastic ERAS champions, buy-in from all providers, involved quality managers, and reliable ancillary support services. At NorthShore University HealthSystem, the biggest impediments during ERAS development have been resource availability, specifically the need to hire more anesthesia technicians and purchase additional ultrasound equipment to aid in regional blocks, and support from all surgical and anesthesia professionals.

ERAS initiatives are important in providing safe care and increasing patient satisfaction in hospital systems across the United States. ERAS interventions have led to a decrease in perioperative morbidity, a reduction in complications and readmission rates, and an improvement in patient rehabilitation and recovery.<sup>5,8</sup> As an added benefit, ERAS protocols have resulted in significant decreases in perioperative opioid usage. To illustrate the safety benefits of ERAS protocols, recent literature and consensus statements for common ERAS interventions will be reviewed (Figure 1). Breakdown of ERAS pathways into individual interventions is for explanation only as ERAS should be thought of as a seamless continuum rather than siloed phases of care. This article will then focus on the associated perceived ERAS benefits to those patients with malignancies. Lastly, this review will describe how ERAS protocols have led to safer perioperative experiences for surgical patients by reducing patient opioid usage.

## ELEMENTS OF ERAS

A number of preoperative ERAS interventions are responsible for providing patient safety and improving outcomes. The first intervention, preoperative education, targets expectations about surgical and anesthetic experiences and has been shown to decrease fear and anxiety and enhance postoperative recovery by decreasing pain and nausea and improving patients' overall well-being.<sup>9</sup> In addition, preoperative education has been shown to accelerate discharge by encouraging early oral intake and mobilization, improving respiratory physiotherapy, and decreasing multiple complications.<sup>10</sup> Preoperative education is accomplished through verbal communication in the surgeon's office, written pamphlets created for specific ERAS protocols, and multimedia means such as on-line websites. A second preoperative ERAS step includes medical optimization, smoking and alcohol cessation,

## Components of an Enhanced Recovery Program

### PREOPERATIVE

- Preoperative Education and Optimization
- Preoperative Fasting Guidelines and Carbohydrate Loading
- Elimination of Mechanical Bowel Preps
- Thromboembolism and Antimicrobial Prophylaxis

### INTRAOPERATIVE

- Multimodal Non-Opioid Analgesics and Antiemetics
- Regional Anesthesia
- Normothermia and Euvolemia
- Minimize and Early Removal of Drains/Foleys/NGs

### POSTOPERATIVE

- Early Mobilization/Ambulation
- Early Nutrition
- Multimodal Non-Opioid Analgesics

Figure 1: Components of an Enhanced Recovery Program.

and prehabilitation. Medical consultation to address issues such as anemia, hypertension, and diabetes has been associated with a decrease in a variety of complications including cardiopulmonary, infectious, bleeding, and other systemic complications.<sup>11</sup> Cessation of smoking and alcohol for four weeks or more prior to elective procedures may decrease postoperative morbidity.<sup>12</sup> Prehabilitation, which improves a patient's functional capacity to help withstand the stress of surgery includes preoperative dietary modifications, relaxation strategies, sleep hygiene, and exercise prescriptions. These programs alone or in combination may reduce length of stay, decrease complications, and accelerate return to preoperative functional state.<sup>13</sup> Finally, carbohydrate loading by ingesting a clear carbohydrate drink two hours before surgery can lessen discomfort and anxiety, maintain lean body mass and muscle strength, accelerate return of bowel function, and reduce insulin resistance.<sup>14,15</sup> This preoperative intervention may help to prevent the catabolic state resulting from preoperative fasting.

Several intraoperative ERAS steps have been shown to enhance patient safety during the perioperative period. Surgical site infection (SSI) bundles and thromboembolic/deep vein thrombosis (DVT) bundles have been successfully integrated into ERAS protocols at many institutions across the United States including Dartmouth, Mayo, and Duke.<sup>16</sup> At NorthShore University HealthSystem, SSI and DVT bundles have been incorporated into all ERAS protocols.

See "ERAS," Next Page

# ERAS Applications

## From “ERAS,” Preceding Page

NorthShore University HealthSystem has experienced a 34% reduction in SSIs (from 4.4% to 2.9%) over the past three years by presumably standardizing several antimicrobial practices including administration of intravenous antibiotics within sixty minutes prior to incision, use of pre-incision chlorhexidine-alcohol skin wipes, antibiotics with bowel preps, and glove/instrument change as well as antibiotic irrigation prior to closure. The ERAS antimicrobial bundle may not only reduce surgical site infections, but has been associated with an improvement in postoperative immune function and a decrease in perioperative inflammatory markers.<sup>17</sup> By utilizing a number of prophylactic measures to decrease venous thromboembolism, NorthShore University HealthSystem has lowered the perioperative DVT rate to zero (from 0.8% to 0%) over the past three years in the ERAS patient population.

Multimodal prophylaxis for postoperative nausea and vomiting (PONV) is another commonly employed ERAS intervention. PONV occurs in 25%-35% of surgical patients and is a primary reason for patient dissatisfaction and increased length of stay. PONV prophylaxis has been shown to reduce PONV rate by 40% and therapy with multiple anti-emetics is additive and preferable.<sup>18</sup>

Strategies to maintain normothermia and euvoolemia are also common in ERAS protocols.

Vigilance in temperature management lowers the incidence of multiple postoperative complications including wound infections, bleeding, cardiac events, and delay in postoperative oral intake.<sup>19</sup> Fluid management is an important but often controversial component of ERAS protocols. While it is debated whether restrictive versus liberal fluid therapy is appropriate for different procedures and different patient subgroups, it is generally accepted that the ultimate goal of fluid management in ERAS patients is to maintain central euvoolemia and to avoid excess salt and water.<sup>20</sup> Maintaining a euvolemic state has been shown to decrease pulmonary and renal complications, accelerate return of bowel function, and reduce surgical site and urinary tract infections.<sup>21</sup> Finally, minimizing drains, tubes, and catheters in surgical patients and removing the necessary ones as early as possible are common and important safety measures, which have also been shown to reduce pulmonary, gastrointestinal, and infectious complications in the postoperative period.<sup>22</sup>

In multiple recent studies, postoperative elements of ERAS protocols have had the strongest association with an expeditious, safe, and complication free recovery.<sup>23</sup> The key postoperative elements are early nutrition and early mobilization. Early nutrition improves insulin resistance, muscle function, and wound healing and lowers the incidence of pneumonia, sepsis, ileus, and surgical site infections.<sup>24</sup> Early mobilization improves muscle strength, promotes

functional organ recovery, reduces pulmonary and thromboembolic complications, and is associated with increased patient satisfaction.<sup>25</sup> These two elements, along with overall protocol compliance and early removal of drains and catheters, are the ERAS elements associated with the greatest impact on an uneventful return to physiologic baseline.<sup>23</sup>

## ERAS AND CANCER CARE

ERAS protocols are beneficial in the perioperative care of cancer patients and positively impact patient survival. Because cancer patients undergoing ERAS protocols can have a rapid recovery to their preoperative functional state, they are able to more quickly return to their oncologic therapy. There is a correlation between the time to continuation of therapy after surgery and improved outcomes and survival for oncologic patients most notably for those with breast, lung, pancreatic, liver, and metastatic colorectal cancers.<sup>26</sup> In one study, cancer patients who underwent ERAS protocols experienced an improved five-year survival.<sup>21</sup> In addition, the reduction in opioid usage associated with ERAS protocols may have the added benefits in this patient population of decreasing cancer recurrence and improving quality of life.<sup>27</sup>

## ERAS AND PAIN MANAGEMENT

An essential component of all ERAS protocols is multimodal pain management. Unlike traditional opioid-centered regimens, comprehensive ERAS multimodal pain management focuses on the use of two or more non-opioid analgesic medications or techniques to minimize or negate the perioperative use of opioid medications.<sup>28,29</sup> This new approach has resulted in improved pain scores, reduction in opioid usage, and a reduction in opioid-related side effects including nausea, vomiting, pruritis, sedation, respiratory depression, ileus, urinary retention, and long-term opioid addiction and dependence.<sup>30</sup> Memtsoudis et al. observed 1.5 million patients who had undergone total knee and total hip replacements and reported an additive positive effect of combining two or more non-opioid modalities resulting in a proportional reduction in postoperative complications, opioid usage, and hospital length of stay.<sup>31</sup> Comprehensive multimodal non-opioid pain management models in ERAS protocols often include combinations of peripheral or central neural blockade with non-opioid analgesics such as non-steroidal anti-inflammatory drugs, cyclooxygenase-2 inhibitors, gabapentin/pregabalin, ketamine, lidocaine, steroids, alpha-2 agonists, or magnesium.

**Table 1: NorthShore University HealthSystem’s Reduction in MMEs (oral morphine milligram equivalents) for Four ERAS Protocols (unpublished data, statistical analysis yet to be executed).**

ERAS® Protocol	Colorectal	Ventral Hernia	Mastectomy w/Implant Reconstruction	Abdominal Hysterectomy
<b>Implementation</b>	<b>10/1/2016</b>	<b>10/1/2017</b>	<b>4/3/2018</b>	<b>8/13/2018</b>
Number of patients	815	150	113	69
<b>Median Length of Stay in Days</b>				
Pre-implementation	4	4	1	3
Post-implementation	2	2	1	2.3
<b>% Patients Utilizing Schedule 2 or 3 Narcotics</b>				
Pre-implementation	100%	100%	91.2%	89.9%
Post-implementation	49.3%	43.2%	31.0%	53.6%
<b>Average Oral Morphine mg Equivalents (MME's) Utilized per Patient</b>				
Pre-implementation	375.9	388.2	79.4	159.1
Post-implementation	81.7	62.9*	14.4	23.8
<b>Overall Reduction in Oral Morphine mg Equivalents (MME's)</b>				
	78.3%	83.8%	81.7%	85.0%

\*One outlier patient accounted for 15% of total MME's for the patient population. Removing the outlier, avg. MME's per patient = 53.3 and % reduction = 86.3%.

## Multimodal Pain Management Important to ERAS Success

### From “ERAS,” Preceding Page

By increasing the number of non-opioid pain management modalities, more effective pain control is achieved with decreased opioid use and opioid related side effects.<sup>31</sup> Based on the study by Memtsoudis et al. the threshold number of non-opioid multimodal pain management techniques required to result in significant benefits in opioid reduction has been estimated to be four.<sup>31</sup> Interestingly, the authors also found that non-steroidal anti-inflammatory drugs and cyclooxygenase-2 inhibitors are the two most effective multimodal pain interventions that lower perioperative opioid usage and decrease overall complication rates.<sup>31</sup> ERAS protocols which implement multimodal pain management can be a safe and effective strategy to improve pain control while minimizing opioid utilization, side effects, and addiction.

At NorthShore University HealthSystem, ERAS protocols have been initiated in patients undergoing colorectal surgery, open ventral hernia repair, breast reconstruction, and abdominal hysterectomy. All NorthShore ERAS protocols utilize multimodal analgesic regimens combined with regional anesthetic blocks with the new long acting bupivacaine liposome injectable suspension. Opioid usage (in addition to many other quality metrics) was tracked in ERAS pathway patients and a reduction in postoperative opioid usage was observed: from 90%-100% pre-ERAS implementation to less than 54% post-ERAS implementation (Table 1). Those patients who required opioids were using minimal dosages, typically two to three doses of an oral opioid. In addition, for all ERAS patients, the amount of oral morphine milligram equivalents (MMEs) used postoperatively was quantified. MMEs are values assigned to opioids that represent their relative potencies and are determined by using an equivalency factor to calculate a dose of morphine that is equivalent for any “non-morphine” opioid. Patients enrolled in ERAS have had a consistent reduction by 78%-86% of MMEs used postoperatively when comparing opioid usage in pre-ERAS and post-ERAS surgical patients (Table 1).

In continuing the commitment to improve perioperative care and to combat the opioid crisis, NorthShore is expanding its ERAS programs by developing initiatives to reduce the doses and quantity of opioids prescribed and used by postoperative patients after discharge. Ongoing analysis of postoperative patient opioid needs at NorthShore will help guide practitioners in prescribing the appropriate quantity of discharge pain medications, since the duration of opioid usage rather than the opioid dosage itself, is more strongly associated with ultimate misuse among opioid naïve postoperative patients.<sup>1</sup>

### CONCLUSION

ERAS care maps and systemization can improve outcomes and safety for patients in the perioperative period. As a result, ERAS strategies are being increasingly utilized in the era of value-based care. With the appropriate resources and provider support, ERAS protocols may lead to significant reductions in opioid usage, complications, and length of stay, and therefore, strong consideration should be given to implementation of ERAS in a variety of surgical subspecialties.

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*The author has no conflicts of interest pertaining to this article.*

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# RAPID Response

to questions from readers

## Nitrogen Contamination of Operating Room Oxygen Pipeline

### Dear Rapid Response:

A little more than a year ago, I was on-call at a mid-sized Florida community hospital. The facility was building a new wing for interventional procedures that was almost completed.

That day, three operating rooms (ORs) were running simultaneously and suddenly a “code blue” was called in one of the ORs, where a colovesicular fistula repair was finishing. I entered the room to see that CPR was underway. The anesthesia professional in the room explained that, during skin closure, he had “trouble ventilating.” He attempted manual ventilation with 100% oxygen, but the patient became bradycardic and then developed asystole. Our anesthesia care team administered one milligram of epinephrine and atropine while CPR was underway and achieved return of spontaneous circulation with an adequate blood pressure. Just then, a nurse contacted me to come to the second OR immediately. Since vital signs were stable and ventilation seemed normal at that point with normal SpO<sub>2</sub>, I left the first patient in the care of the surgeon and anesthesia professional.

I entered the second OR and the anesthesia professional in that room explained that the patient abruptly became hypoxic and then bradycardic despite being ventilated with oxygen alone. As I began to help troubleshoot, I was called emergently to the third OR. Another anesthesia professional helped resuscitation efforts in OR 2.

Entering the hallway, I noticed the oxygen manifold high-pressure alarm was emitting a loud noise indicating high pressure at 75 psig.

When I arrived in the third room, the anesthesia professional was ventilating that patient using a bag-valve-mask device connected to a portable oxygen E-cylinder. She stated that

there was a “problem with the anesthesia machine,” and she felt most comfortable using the independent oxygen source for ventilation until help could arrive. I quickly checked the anesthesia machine in that room and found it fully functional. Still concerned about the central gas supply, I disconnected the machine from the wall oxygen source and continued the case using the cylinder supply. At that point, I hypothesized that a nitrogen source connected to the oxygen manifold could explain the findings in all three ORs. As a former nuclear engineer, I was familiar with pipe testing and errors due to incorrect valve line-ups.

Fortunately, there were no sequelae for any of the patients. However, one of the patients remained intubated and was transferred to the ICU. The ICU (one floor above the new OR) shared the same medical gas system, and therefore, I alerted the ICU staff to use only portable oxygen cylinders until the problem had been completely resolved. Our chief of medical staff and chair of surgery, along with our chief executive officer, all decided to close the ORs until the problem was evaluated and rectified. The ICU continued to operate on portable oxygen cylinders but, in the interim, planned to transfer any new ICU admissions to a sister hospital several miles away.

Analysis of the electronic medical record data revealed a 10-minute period where the O<sub>2</sub> concentration dropped below 10% despite delivering “only oxygen” at 10 liters per minute (Table 1). During most of that period, the oxygen concentration was essentially 0%. When data were evaluated for each OR chronologically, it appeared that a bolus of nitrogen was introduced into the oxygen piping and traveled from room to room until it was washed out by oxygen flow. Each room dropped oxygen concentration about two minutes apart sequentially along the piping run.

The hospital facilities manager inspected the system with our piping contractor, and next morning the system was deemed fit for use.

A Root Cause Analysis (RCA) was performed and identified the following: Contractors were testing gas piping in a new section of the hospital. Although “proper active system isolation” was in effect, “someone” doing other maintenance work in the area “opened an isolation valve briefly,” which allowed 150 psi nitrogen to displace oxygen in the active piping limb. Hospital Risk Management and the facilities manager stated that the contractor was “fully licensed and trained.”

#### The RCA report recommended that:

1. Future medical gas testing and maintenance shall be done on “off-hours” if possible, and that management will notify all staff about planned testing.
2. During any future testing, isolation valves shall be checked, tagged, and locked.
3. During future pipe testing, management will allow no other maintenance work in the vicinity of isolation valves or pipe testing equipment.

I hope that this incident will raise awareness about the potential for adverse patient events that can occur during construction and maintenance of medical gas piping systems. I have been unable to locate published reports of a similar incident that have not resulted in death or serious harm to patients. There is a sharp increase planned in community hospital expansion projects over the next few years.<sup>1</sup> I fear that, as a result, we may see more of these misadventures nationwide.

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*The author has no conflicts of interest pertaining to this article.*

**Table 1: Data From Anesthesia Record System in One Affected OR**

Minutes	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
O <sub>2</sub> (L/Min)	1	1	1	1	1	1	1	10	10	10	10	10	10	10	10	10	10	10
FiO <sub>2</sub> (%)	53	33	26	18	13	9	1	1	1	1	0	1	1	3	3	1	67	95
SpO <sub>2</sub> (%)	100	100	99	99	97	88	76	32		2								100
Pulse Rate	84	83	83	80	83	80	84	89		121								132

Red shading indicates the period during which CPR/ACLS was ongoing.

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See “Nitrogen Contamination,” Next Page

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# Nitrogen Contamination of Oxygen Supply: Prevention and Response

by Jan Ehrenwerth, MD

### From "Nitrogen Contamination," Preceding Page

Bulk oxygen delivery systems and medical gas pipelines have the potential to be a serious patient safety hazard. Reports of problems with these systems date back over 50 years. For example, Bancroft and colleagues<sup>1</sup> reported 18 major problems with their liquid oxygen delivery system in one year.

The potential problems can involve existing systems as well as new construction. Hazards with existing systems include running out of oxygen, filling the oxygen supply with the wrong gas, and pipeline leaks. Problems with new construction include contamination of the pipeline with debris, crossed gas lines, improper construction of the pipeline and brazing of joints, and improper verification and testing of the new pipeline.

The National Fire Protection Association (NFPA) publishes codes for medical gas supplies under the title "NFPA-99 the Health Care Facilities Code."<sup>2</sup> Chapter 5 (Gas and Vacuum Systems) gives very specific instructions as to what procedures the installer and inspectors must follow during construction. In addition to following the codes, all personnel involved in medical gas pipeline installation must have specific training and certification. The installer must be American Society of Sanitary Engineering (ASSE) 6010 certified. Similarly, the inspector must be ASSE 6020 certified, and the verifier needs to hold an ASSE 6030 certificate. It is important to note that the installer, inspector, and verifier cannot be the same person.

When installing a new medical gas pipeline the contractor must consider two important factors: the code, which tells the installer what to do, and his certification and training, which tells him how to do it. If these rules are followed then mishaps will not occur. First, the installer does an initial purge with nitrogen. This removes debris that has accumulated in

the pipeline during construction. Next, the pipeline is pressurized to 150 psi with nitrogen, and every joint is inspected for leaks. The pipeline is then depressurized and tested for cross-connections. Finally, each outlet is purged to remove particulate matter, and a 24-hour "standing pressure test" is completed. The connection to the main system cannot be done until all of the nitrogen testing is completed. Finally, a 6030 verifier shall test all installations.

If an anesthesia practitioner encounters a potential problem with the oxygen supply, what is the proper procedure to follow? The practitioner will first be alerted to a problem by the oxygen analyzer on the anesthesia machine. Events like the one reported by Dr. Gilfor in this issue of the *APSF Newsletter* underscore the importance of a functioning oxygen monitor with the alarms properly set prior to every anesthetic. If the inspired oxygen concentration falls below 20%, the practitioner should immediately suspect a problem. There are two options to safely care for the patient in this situation. First, the patient can be disconnected from the anesthesia machine and ventilated with a self-inflating bag or Mapleson type circuit and a portable oxygen cylinder. Alternately, the emergency oxygen tank(s) on the machine can be utilized. The anesthesia practitioner must remember that the pressure in the oxygen tanks is reduced to 45 psi, but the pressure in the hospital pipeline is 50-55 psi. A previous report of this same problem noted that turning on the oxygen tanks on the anesthesia machine did not solve the problem due to the pressure in the supply lines.<sup>3</sup> Therefore, the hoses from the central supply must be disconnected to insure that oxygen will flow from the tank supply.

*Dr. Ehrenwerth is professor emeritus, Yale University School of Medicine, New Haven, CT USA.*

*The author has no conflicts of interest pertaining to this article.*

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### Editor's Note:

Unfortunately, there is a history of events like this being reported to the APSF.<sup>1-3</sup> We will continue to publish these reports as a reminder that nitrogen contamination of oxygen supplies is completely preventable. More importantly, patient injury is completely preventable in this situation, but requires continuous oxygen monitoring, vigilance, and ready access to an alternate supply of oxygen.

*Dr. Feldman is chair, APSF Committee on Technology, and professor of Clinical Anesthesiology Children's Hospital of Philadelphia Perelman School of Medicine, Philadelphia, PA.*

*Dr. Feldman has received consulting compensation from Micropore, Dräger Medical, GE Medical, and Medtronic.*

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## APSF Legacy Society Announcement

by Mark A. Warner, MD, APSF President

I am pleased to announce the establishment of the **Anesthesia Patient Safety Foundation (APSF) Legacy Society**. The APSF Legacy Society will honor those who make a gift to the foundation through their estates, wills, or trusts. Legacy Society members help safeguard the future of patient safety by ensuring that safety research and education, patient safety programs and campaigns, as well as a national and international exchange of information and ideas will continue on behalf of the profession for which we are so deeply passionate.

### BECOME AN APSF LEGACY SOCIETY MEMBER:

Legacy Society members are partners in the future of anesthesiology. To become an APSF Legacy Society member, simply inform APSF of your planned gift by contacting Sara Moser, director of development at [moser@apsf.org](mailto:moser@apsf.org). We have a complimentary guide that explains more about planned giving that we can provide you as well as a membership form we ask you to complete. You do not need to provide documentation of the gift type or amount. There is no minimum gift amount for Legacy Society membership.

Members of the Legacy Society will be noted on our website and in each issue of the APSF Newsletter.



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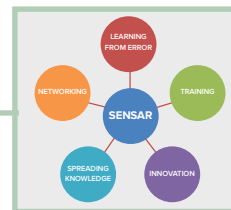
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