

New Developments for the Management of Sepsis

by Todd Dodick, MD; Steven Greenberg, MD; and Michael O'Connor, MD

An experienced health care provider can identify the septic patient with barely a glance, but were you to ask them to define sepsis, many providers would struggle to provide a clear definition. This difficulty likely stems from a failure of understanding of the underlying pathophysiology of sepsis. A new consensus definition, released in early 2016, sought to more clearly define sepsis and septic shock.¹ According to these new definitions, sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection, while septic shock is a subset of sepsis in which profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone.

Previous guidelines used 4 criteria to identify patients with the systemic inflammatory response syndrome (SIRS), including temperature, heart rate, respiratory rate, and white blood cell count—measures that have been shown to be highly sensitive but lacking specificity, especially in the elderly.² The new guidelines abandon these SIRS criteria. Instead, they focus on the Sequential Organ Failure Assessment (SOFA) score—a measure that determines the extent of a patient's organ

function or rate of failure (and incorporates a scoring system for respiratory, cardiovascular, hepatic, coagulation, renal, and neurological systems).³ The SOFA score has been associated with increased mortality in intensive care units.³ A score of 2 points or more above the patient's baseline at the onset of sepsis has been associated with an in-hospital mortality of 10%.¹ SOFA score may

Quick Sepsis-Related Organ Assessment (qSOFA)			
Points	Respiratory Rate	Altered Mental Status	Low Blood Pressure
	≥22 breaths per min	Glasgow coma scale <15	SBP ≤100 mmHG
Points	1	1	1

qSOFA ≥2 suggests a poorer outcome and should alert clinicians of possible infection when previously not known.

Information adopted from:

Singer M, Deutschman DS, Seymour CW, Shankar-Hari M, et al. The third international consensus definitions for sepsis and septic shock (Sepsis-3). *JAMA* 2016;315:801-810.

be useful to identify acutely ill patients coming to the operating room or other procedural areas under the care of an anesthesia provider.

A new rapid, bedside tool to identify sepsis at presentation was proposed by the expert panel which released the new definition. The quickSOFA score (qSOFA) has 3 criteria—respiratory rate >22 bpm, altered mental status, and systolic blood pressure <100 mmHg. Using qSOFA, any provider may quickly identify upon initial evaluation any patient meeting at least 2 of the criteria as likely having sepsis, and initiate immediate appropriate therapy and further evaluation of organ dysfunction.⁴ This may prove to be useful in the emergency department and other ambulatory settings. However, further attempts at validating qSOFA are forthcoming.

The 2012 Surviving Sepsis Campaign guidelines for the management of severe sepsis outline and still remain the foundations of care—early recognition, source control, resuscitation, and timely antibiotic therapy.⁵ One recent

See “Sepsis,” Page 5

Perioperative Fluid Management: Cheers to the Dream of Moderation

Michael G Mythen, MBBS, MD, and Michael PW Grocott, BSc, MBBS, MD

Fluid management is a fundamental component of the care we give our patients undergoing surgery. Establishing intravenous access and setting up a bag of fluid to flow into a vein is so much a part of everyday working life that we rarely give it much thought. We each have our own personal rationale for our chosen pattern of fluid administration and we probably think that we have pretty standard, mainstream patterns of behavior in our care and deliver a good outcome for our patients. Yet a high degree of variability in both the type and amount of fluid that our patients receive during major surgery is repeatedly reported in the literature, and at the extremes is associated with poor outcome.¹⁻³

For example, Lilot et al. recently published an analysis of clinical data from 6,000 patients undergoing intra-abdominal surgery at UC Irvine and Vanderbilt University Medical Centers.¹ They reported the variation in crystalloid administration in a variety of uncomplicated elective intra-abdominal surgery cases with minimal blood loss. The mean “corrected crystalloid infusion rate” across all providers was 7.1 (SD 4.9) ml/kg/h. Individual provider means ranged from 2.3 to 14 ml/kg/h. They concluded that the “final regression model strongly favored personnel as predictors (of administered fluid volume) over other patient predictors.”¹ Therefore, the major determinant in this particular study of how much fluid a patient received on the day of surgery was not a change in hemodynamic variables

(heart rate, blood pressure), duration of surgery, or blood loss, but the particular anesthesia provider who had been assigned to do the case. In an applied example, the authors showed how a patient weighing 75 kg undergoing a 4-hour procedure with minimal blood loss could receive anywhere between 700 and 5400 ml of crystalloid during surgery, depending on which anesthesia provider had been allocated.¹

More recently, Thacker et al. published a study describing fluid administration practices in a large cohort from the Premier Research Database including adult patients having colon, rectal, or primary hip or knee surgery.³ These investigators explored the relationship between intravenous fluid utilization

See “Fluid Management,” Page 8

TABLE OF CONTENTS

Articles:

New Developments for the Management of Sepsis Cover
 Perioperative Fluid Management: Cheers to the Dream of Moderation Cover
 Low Tidal Volume Ventilation in the Operating Room—Where Are We Now?Page 3
 APSF Awards Two Safety Scientist Career Development AwardsPage 13
 HAIs: When in Doubt, Blame Anesthesia. Could They Be Right?Page 14
 A Japanese Perspective on Patient SafetyPage 18
 Developing Patient Safety Leaders: Leadership Fellows Share InsightsPage 20
 Ultrasound-Guided Subclavian Vein Catheterization: Evidence and PracticePage 23
 From APSF Educational Videos to Your Practice: How to Make it HappenPage 26

Letters, Q&A and Dear SIRS

Letter to the Editor: Use of Capnography during Moderate Sedation by Non-Anesthesia Personnel in Various Clinical SettingsPage 7
 Letter to the Editor: Eliminating Ratio Expressions on Single Entity Drug ProductsPage 7
 Letter to the Editor: Expert Clarifies Complexity of Unintended ICD FiringPage 10
 Dear SIRS: Why Do The Gauss Lines Matter?Page 16
 Dear SIRS: Safety Issues With Gas Scavenging System in GE Avance and GE Aespire Anesthesia MachinesPage 17
 Q&A: Reader Questions Fire Risk of Petroleum-Based ProductsPage 25

APSF Announcements

Corporate Advisory CouncilPage 4
 Save the Date for APSF Workshop: Distractions in the Anesthesia EnvironmentPage 10
 APSF Corporate Supporter PagePage 11
 APSF Donor PagePage 12
 APSF Resident Quality Improvement (RQI) Recognition AwardPage 19
 APSF Website Offers Online Educational DVDsPage 22



NEWSLETTER

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Low Tidal Volume Ventilation in the Operating Room—Where Are We Now?

by Tao Shen, MBBS, and Edward A. Bittner, MD, PhD, MSED

High tidal volume (TV) (10-15 mL/kg) mechanical ventilation has been historically encouraged for anesthetized patients in the OR, especially for abdominal and thoracic procedures. This practice was based on a study published in the *New England Journal of Medicine* in 1963. It followed a series of 18 patients undergoing laparotomy and showed higher TV resulted in less atelectasis, less acidosis, and improved oxygenation compared to lower TV.¹ However, over the last 2 decades, laboratory and clinical studies have linked higher TV, especially with higher inflation pressure, to a greater degree of lung injury. Indeed, the concept of lung protective ventilation was popularized by the landmark Acute Respiratory Distress Syndrome (ARDS)—net study published in 2000 showing lower TV (6-8 mL/kg) improves survival in ventilated critically ill patients with ARDS.² This finding prompted a categorical change in ventilatory practice in critically ill patients with lung injury, and raised questions regarding the benefit of low TV ventilation for patients with uninjured lungs.

Over the past few years, a growing number of studies have related improved postoperative outcomes with intraoperative low TV ventilation.³ Despite this growing body of evidence, slow adoption of lung protection in the OR has occurred. Since choosing lower TV is easy to implement and incurs no additional cost, shouldn't use of low TVs be considered the approach to ventilate patients during surgery? This article provides a brief overview of the physiological rationale and clinical evidence in support of low TV ventilation in the operating room in an effort to inform and provide practical guidance for clinicians.

Lung Protective Ventilation—Physiological Rationale

Mechanical ventilation can cause lung injury (known as ventilator-induced lung injury (VILI)) via a number of different mechanisms, including repeated over-distension of aerated lung (volutrauma), cyclic recruitment and de-recruitment of lung units (atelectrauma), and application of high plateau pressures (barotrauma).⁴ The deleterious effects of mechanical ventilation appear to be mediated by localized inflammation and the systemic release of inflammatory cytokines (biotrauma). Biotrauma not only promotes lung injury, but can also contribute to systemic injury due to the spillover of these inflammatory mediators into the systemic circulation, inducing remote organ dysfunction.⁵

General anesthesia affects lung function primarily by the loss of muscle tone, which promotes the development of lung atelectasis. The development of atelectasis is very common and occurs in more than 90 % of subjects undergoing general anesthesia, especially when accompanied by neuromuscular blockade.⁶ Lung atelectasis may also promote the development of VILI by overdistension of non-collapsed lung units and by the cyclical opening and closing of adjacent collapsible lung units.

Animal studies of VILI have frequently used a multiple-hit approach in which lung injury was first triggered by a preceding insult (e.g., systemic inflammation or sepsis) and then amplified by the harmful effects of large TV.^{7,8} However, studies have also demonstrated that ventilation with high TV alone – without a preceding insult – can also induce VILI.⁹ Of particular note, the majority of animal models of VILI have used relatively short periods of ventilation, resembling the clinical conditions of the operating room.

These findings suggest that ventilation strategies that use high tidal volumes during surgery may be harmful. Furthermore, it can be surmised that the potential harmful effects of mechanical ventilation may be minimized by the use of lower TVs that cause less lung distension, coupled with positive end-expiratory pressure (PEEP), or recruitment maneuvers to maintain lung volume.

Clinical Evidence for Lung Protective Ventilation

A number of small clinical studies of intraoperative ventilation suggested that low TV ventilation could improve pulmonary mechanics and oxygenation,^{10,11} reduce local production of inflammatory mediators,¹² and shorten duration of postoperative ventilation.¹³ A pooled meta-analysis of 8 of these studies also suggested that low TV intraoperative ventilation strategies were associated with a reduced incidence of postoperative pulmonary complications.¹⁴ Three recent randomized controlled trials (RCTs) in patients undergoing a variety of surgeries have provided further evidence for the benefits (including improved postoperative pulmonary function and reduced pulmonary complications) of intraoperative ventilation with low TV (6-7 mL/kg predicted body weight (PBW)).^{15,16,17} It is important to emphasize that, in all 3 trials, lung-protective ventilation consisted of a bundle of measures: with differences in the size of TVs, levels of PEEP, and use of recruitment maneuvers; as such, it is not possible to ascertain which protective measure caused most benefit. However, a recent individual patient data

meta-analysis, which included data from these 3 trials, suggested that benefit from lung-protection was best explained from TV reductions, and not from higher levels of PEEP.³

While it is important to acknowledge that using low TV without PEEP promotes atelectasis formation, the optimal PEEP for intraoperative lung protection remains unclear. One recently published multicenter RCT of low TV (8 mL/kg) in non-obese patients undergoing abdominal surgery compared intraoperative ventilation with low levels of PEEP (0 – 2 cm H₂O) versus high levels of PEEP (12 cm H₂O).¹⁸ There were no differences in the incidence of postoperative pulmonary complications between groups.¹⁸ However, the use of higher PEEP levels was associated with intraoperative hypotension and a greater need for vasoactive drugs. Despite these findings other patient populations may benefit from higher levels of PEEP such as those who are obese or who are undergoing laparoscopic abdominal surgery with gas insufflation that may increase atelectasis. Still, the optimal combination of PEEP and TV, as well as the additional benefits of recruitment maneuvers is unknown.

Current Practice and Moving Forward

Low TV ventilation is increasingly being employed in the operation room, as suggested by a recent report on intraoperative ventilation practices in 5 large university hospitals in the US.¹⁹ In that study, almost 60% of cases used median tidal volumes < 8 mL per kg of PBW in 2013 compared with less than 25% of cases in 2005. While it is certainly possible that further expansion of the practice of intraoperative low TV ventilation could result in clinical benefit for some patients, it is important to consider whether there is any potential harm associated with widespread adoption of this practice. It has been argued that for some patients, ventilation with low tidal volumes can promote atelectasis, increase patient-ventilator dys-synchrony, and increase patient effort during spontaneous ventilation, which could cause fatigue and lung injury.²⁰ Each of these detrimental effects could therefore offset the potential beneficial effects of low TV. Since a reduction in lung stress during mechanical ventilation is the mechanistic explanation for the beneficial effects of lower TVs, the selection of lung protective ventilation should likely be individualized. When employing low TV ventilation, clinicians should consider the type and duration of procedure, preexisting lung

See “Low TV,” Next Page

Evidence Suggests Low to Moderate TV May Be Beneficial

“Low TV,” From Preceding Page

compliance, and the presence of pulmonary disease, as well as the consequences on lung stress if a patient is allowed to breathe spontaneously or will receive controlled ventilation.

Going forward, a number of questions regarding the specifics of intraoperative lung protective ventilation remain unanswered including the optimal levels of driving pressure, the benefits of lung recruitment maneuvers, and selection of optimal levels of PEEP. Fortunately, a number of randomized control trials are underway to better characterize methods of lung protection in specialized populations.²¹⁻²³ The results of these trials have the potential to further improve the safety of intraoperative ventilation. Until that information is available, the existing evidence would suggest that controlled ventilation using low tidal volumes together with the use of low to moderate levels of PEEP is a safe practice and likely beneficial for the majority of patients during surgery.

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Pulse Pressure Variation May Be Useful Predictor of Volume Responsiveness

“Sepsis,” From Page 1

study suggested that time to administration of appropriate antibiotic therapy may impact both ICU and hospital length of stay.⁶ In many septic patients, source control may require a trip to the operating room (OR), interventional radiology suite, or other procedural areas under the care of an anesthesia provider.

Resuscitation of the Septic Patient in the Operating Room

It is likely that the anesthesia provider will continue resuscitation efforts that have been ongoing in the ICU, Emergency Department (ED), or hospital floor in the OR. Care of the septic patient may require invasive monitoring, in addition to the standard monitors. An arterial line may serve as a reliable monitor of arterial blood pressure to guide resuscitation. Patients may require central venous access as well for administration of fluids when peripheral intravenous access is inadequate or for long-term administration of vasoactive medications.

The identification of which patients will respond to volume resuscitation in sepsis is important. While central venous pressure (CVP) is a poor predictor of fluid responsiveness,⁷ it remains in widespread use as an indicator of volume status.⁸ Studies suggest that pulse pressure variation on an arterial line (PPV-variation in pulse pressure between inspiration and expiration with positive pressure ventilation) may be superior to central venous pressure as a predictor of volume responsiveness in septic patients, and may be used whenever clinical circumstances allow.⁹ However, PPV may be invalid in several scenarios, including but not limited to a non-sinus rhythm, low tidal volume ventilation, ventilator-patient dyssynchrony, altered chest wall or pulmonary compliance, pulmonary hypertension, elevated intra-abdominal pressure, or with an open chest.^{9,10}

In 2001, Rivers et al. published his landmark article and an algorithm for early goal-directed resuscitation (EGDT) of the septic patient using mean arterial pressure (MAP), CVP, and central venous oxygen saturation (ScvO₂) to guide resuscitation within the first 6 hours of admission, primarily in the ED.¹¹ This approach, quickly adopted by many providers, was recently compared to standard practice in a series of studies. While EGDT was not shown to be a superior approach to standard practice, it was not inferior.¹²⁻¹⁴ While consensus has not been reached on a universal set of hemodynamic goals to guide resuscitation of the septic patient, EGDT of patients with septic shock remains a reasonable algorithm to manage these patients, with or without invasive monitors. The question of which measures and what goals to use for titration are evolving, and will almost certainly be influenced by new expeditious tools that are developed to identify septic patients.

Table 1: New Definitions and Diagnostic Criteria

	Sepsis	Septic Shock
Definition	Life-threatening organ dysfunction caused by a dysregulated host response to infection	Sepsis with profound circulatory, cellular, and metabolic abnormalities. Associated with a greater risk of mortality than with sepsis alone
Criteria	Infection + SOFA score of at least 2	Hypotension requiring vasopressor support to maintain MAP >65 mmHg and lactic acid >2 mmol/L refractory to fluid resuscitation

Table 2: Take Home Points

Early recognition allows early treatment (Table 1)	
Source control is paramount, if it is possible	
Timely, appropriate antibiotic therapy is an important determinant of outcome	
Resuscitation	<ul style="list-style-type: none"> • Goal-directed using ScvO₂ and/or lactate clearance • EGDT is reasonable, as no alternative has been demonstrated to be superior • PPV to assess fluid responsiveness • Target MAP 65mmHg • Balanced salt solution (e.g., lactated Ringer's) or 5% albumin are appropriate • Norepinephrine as first-line vasopressor, vasopressin 0.03 units/min as adjunct • 200 mg/d hydrocortisone if refractory shock on multiple vasopressors • Hb>7 g/dl unless signs of tissue hypoxia or other indication for higher threshold
Avoid	<ul style="list-style-type: none"> • Tight glycemic control • Hetastarch

Maintaining Blood Pressure

Mean arterial pressure is a preferred choice as a parameter to monitor in the resuscitation of the septic patient.¹⁵ The Rivers trial among others somewhat arbitrarily chose a MAP of 65 mmHg as a target to maintain tissue perfusion. A more recent multicenter, randomized study comparing a low-MAP target (65-70 mmHg) to a high-MAP target (80-85 mmHg) in septic patients found no difference in mortality between the 2 groups.¹⁶

The maintenance of an adequate blood pressure will typically require some combination of fluid administration and vasoactive support. For the resuscitation of the septic patient, both crystalloid and colloid may be considered. Balanced salt solutions like Lactated Ringer's or Plasma-Lyte may cause less acidemia and kidney injury than saline solutions in surgical patients,¹⁷ and are associated with lower in-hospital mortality in sepsis.¹⁸ Albumin has been shown to be non-inferior to, and possibly superior to, crystalloid for the resuscitation of the septic patient and particularly in the septic shock patient.^{19,20} However, its benefit should be weighed against the significant incurred cost. At present, starch solutions should be avoided for resuscitation in sepsis, as they may increase mortality, risk of acute kidney injury, and the need for renal replacement therapy.²¹

If fluid administration is not sufficient to maintain adequate blood pressure, norepinephrine may be considered as the vasopressor of choice. Norepinephrine has been associated with a lower mortality and lower risk of tachyarrhythmias than dopamine.²² Adding vasopressin to norepinephrine at a dose of 0.03 U/min can be considered as a catecholamine-sparing adjunct to norepinephrine, but has not shown to decrease mortality.²³ If norepinephrine and vasopressin at maximal doses cannot adequately maintain MAP >65 mmHg, epinephrine may be added or substituted. Phenylephrine is typically a second- or third-line agent to maintain MAP in septic patients but can also be used in those patients with arrhythmogenic complications of catecholamines.⁵

Monitoring of Resuscitation

One method of estimating the adequacy of resuscitation is the measurement of central venous blood oxygen saturation (ScvO₂). ScvO₂ drawn from the sinoatrial junction, while not equivalent to mixed venous oxygen saturation (SvO₂) drawn from the pulmonary artery, correlates well in the initial resuscitation period in sepsis.^{24,25} This correlation may become less consistent as early as 6 hours into resuscitation.²⁶ In sepsis, ScvO₂ is normally elevated well above baseline. In the Rivers EGDT trial, the protocol used a target ScvO₂ of at least 70% to signify

See “Sepsis,” Next Page

Lactate Clearance Can Help Determine Adequacy of Resuscitation

“Sepsis,” From Preceding Page

an adequate balance of oxygen delivery relative to utilization. Despite the use of ScvO₂ in the Rivers trial, there is wide variability in the use of ScvO₂ in the resuscitation of septic patients, largely due to the requirement for central venous access.²⁷

An alternative to venous oxygen saturation for the evaluation of the circulation, and one that can be used in the absence of a central line, is serum lactate level and lactate clearance. By comparing the lactic acid level of 2 blood samples drawn at least 2 hours apart, the “lactate clearance” can be calculated. This difference can be used to assess the adequacy of resuscitation in septic patients. This method has been shown to be non-inferior to ScvO₂ use, with a target decrease in lactate of at least 10%.²⁸ The addition of lactate clearance to the traditional Surviving Sepsis Campaign bundle may lead to decreased mortality in sepsis patients.²⁹

Transfusion of blood and the infusion of inotropes can also be used to both increase ScvO₂ and decrease lactate levels. However, a recent multicenter randomized trial has subsequently shown that there is no benefit of using a transfusion threshold of 9 g/dl over a threshold of 7 g/dl in sepsis.³⁰ Because most patients will have central venous saturations above 70%, it is relatively uncommon for septic patients to require or be treated with inotropes such as dobutamine.

Etomidate

Although induction with etomidate has minimal cardiovascular depression relative to other induction agents, it suppresses adrenal steroidogenesis by directly inhibiting 11 β -hydroxylase.³¹ The administration of a single dose of etomidate for intubation in patients with sepsis increases the risk of adrenal insufficiency, and possibly the risk of mortality as well.^{32,33} Therefore, etomidate should be used with caution in this patient population.

Steroid Replacement

Early steroid replacement has not been demonstrated to be beneficial for all patients in septic shock.³⁴ Patients who remain hypotensive despite ongoing fluid resuscitation and require support with multiple vasopressors are still often treated with administration of 200 mg of hydrocortisone daily in divided doses. Once vasopressors have been weaned off, corticosteroids may be discontinued as well.⁵

Tight Glycemic Control

Earlier in the 21st century, practice patterns and randomized trials favored a tighter glycemic control approach (defined as blood glucose 80-110 mg/dl).³⁵ However, a larger international multicenter trial investigating a broader critically ill population subsequently favored a less tight glycemic control approach of (<180 mg/dl) in the ICU.³⁶

Based on these data, a reasonable perioperative goal is a blood glucose <180mg/dl.

Conclusions

With experience in monitoring and resuscitation, the anesthesia provider is ideally suited to care for the septic patient. While a universal set of goals for resuscitation of the septic patient remains elusive, the anesthesia provider has the knowledge and experience to interpret hemodynamic data and apply those principles discussed here to care for these patients. Despite imperfect criteria for defining sepsis, the goals of early recognition, source control, timely antibiotic therapy, and resuscitation remain the foundation for treatment of sepsis.

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See “Sepsis,” Next Page

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“Sepsis,” From Preceding Page

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Letter to the Editor:

Use of Capnography during Moderate Sedation by Non-Anesthesia Personnel in Various Clinical Settings

To the Editor:

Capnography is a waveform that shows evidence of breathing; it monitors the partial pressure of carbon dioxide (CO₂) in the exhaled air, also known as end tidal CO₂ expressed in a graphical pattern on the monitor. It is used quite extensively in anesthesia and critical care settings.

Capnography provides information of breath-to-breath ventilation, the EtCO₂ can predict hyperventilation from inadequate analgesia or sedation, as well as hypoventilation from over-sedation or other potentially life-threatening causes. The diagnosis of respiratory difficulty from various obstructive mechanisms can be deduced from capnography.

Capnography has been known to assist in predicting and averting impending respiratory arrest situations in hospitalized, critically ill patients who show significantly elevated CO₂ levels (hypercapnia).

Moderate sedation is the use of sedative medications (anxiolytics—midazolam, diazepam; opioids—morphine, fentanyl; anesthetic solutions—propofol, etomidate, ketamine) to provide patients with comfort, relaxation, amnesia, and analgesia in order to perform certain clinical procedures in various settings like cardiac catheterization laboratories, endoscopy suites, radiology, emergency rooms, ambulatory surgical centers, and doctors' offices.

Anesthesia personnel usually provide moderate sedation for procedures and safe techniques are encouraged with capnography being of paramount importance alongside other standard monitoring techniques (pulse oximetry, blood pressure, EKG). Capnography during moderate and deep sedation was added by the American Society of Anesthesiologists as part of the Standards for Basic Anesthetic Monitoring, effective July 1, 2011.

Capnography use in 100% of moderate and deep sedation cases in hospitals should be encouraged. The monitoring of ventilation using capnography is vital to titrating sedatives for which different patients have variable levels of sensitivity. It will provide early warning signs of adverse respiratory events as well as assist in better patient care and outcomes.

Conclusion:

Capnography should be a standard monitor in all situations of health care management in which moderate sedation is used, regardless of which health care provider is administering the sedation.

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Letter to the Editor:

Eliminating Ratio Expressions on Single Entity Drug Products

To the Editor:

We would like to update the Anesthesiology community on recent changes in the way that ratio expressions will be labeled on medications with single entity drug labels. The latest update of the United States Pharmacopeia (USP) and The National Formulary (NF) (USP39-NF34), will become official on May 1, 2016, and will no longer allow the use of ratio expressions on single entity drug products (U.S. Pharmacopeia. Labeling <7>, Ratio Expression of Strength. USP 38NF 33, 2015). The most important drug affected in the field of anesthesiology will be epinephrine, which up until now has been supplied as either a 1-mL ampule of a 1:1,000 solution (usually used subcutaneously for acute bronchospasm) or as a 10-mL vial of a 1:10,000 solution (usually used intravenously as a cardiostimulant agent). The 1:1,000 solution will only be displayed as 1 mg/mL, and the 1:10,000 solution will be displayed as 0.1 mg/mL. Other medications affected include isoproterenol

(a 1:5,000 injection will be expressed as 0.2 mg/mL), and neostigmine (a 1:1,000 injection will be expressed as 1 mg/mL). The May 1, 2016, date will allow manufacturers and drug information systems time to make these changes. The Institute for Safe Medication Practices (ISMP) had previously petitioned USP to make this change because of an ongoing stream of serious errors where different ratio expressions were confused with one another (www.ismp.org/sc?id=1641). An important exception will be the description of the epinephrine contained within local anesthetic solutions, for example, as lidocaine 1% with epinephrine 1:100,000 injection, or bupivacaine 0.25% with epinephrine 1:200,000 injection. These local anesthetic solutions will retain ratio expressions for the epinephrine component because a decimal notation for such a low strength could easily be misread.

All anesthesiology providers should be aware of the upcoming changes, and should use the new dosing nomenclature when referring to these med-

ications after the changes have been introduced. Once the labels change and they no longer contain the ratio expressions, drug storage labels and orders for these drugs must be communicated using doses expressed in metric weights to avoid confusion. For example, if a prescriber leading a code team calls out for “1:10,000 epinephrine” and the product label no longer contains this ratio expression, practitioners could become confused and administer the wrong strength. In clinical situations that require epinephrine, it will need to be ordered as an absolute mcg or mg dosage and the route specified.

Sincerely,

Ronald S. Litman, DO, Medical Director

Michael R. Cohen, RPh, MS, President

*Institute for Safe Medication Practices
Horsham, PA*

Goal-Directed Fluid Management Makes Sense

“Fluid Management,” From Page 1

tion on the day of surgery and outcomes. Regression models were developed to determine associations between liberal or restrictive day-of-surgery fluid volumes and the likelihood of various outcomes. When compared with the 50% of patients who received moderate volumes (middle 2 quartiles by volume of fluid administration), they found significant associations between liberal fluid administration (upper quartile) on the day of surgery and increased total costs (odds ratio 1.10-1.50) and length of stay (odds ratio 1.10-1.40) in all patients, as well as increased presence of postoperative ileus in patients undergoing colorectal surgery. They also observed that restrictive fluid utilization (lower quartile) was associated with worse outcomes.³

This seemingly chaotic, and certainly highly variable, administration of intravenous fluids is also seen in reports of randomized controlled trials. In 2 recent examples the range of “maintenance fluid” advocated in the protocols ranged between 10ml/kg/hr of Lactated Ringer’s solution and 1ml/kg/hr of 5% Glucose. A huge difference in salt and water load resulted, and yet the results are reported as though we are comparing apples with apples.²

Finally, and arguably pertinent to the notion that there is extraordinary variation in fluid administration practices, there are increasing

reports of the rare but disastrous adverse outcome of unexpected blindness following spine surgery.^{4,5} In several articles published in the winter issue of the 2013 *APSF Newsletter*, excessive crystalloid administration, coupled with a relative under-utilization of colloid, was highlighted as a possible causative factor.⁴ One case-control study identified high crystalloid and low colloid volume administration as a risk factor for developing postoperative visual loss from ischemic optic neuropathy after major spine surgery.⁵

So why does this conundrum continue? The plea for a more measured approach to fluid management echoes down the decades. The late Tom Shires (former professor and chairman of Surgery, Southwestern Medical School, Dallas) is credited with being an early advocate for the need to fill the “third space.”⁶ Those of us who trained in the last century learned of the mysterious “third space,” a secret place lurking deep within the human body that, under certain circumstances, would consume intravenous fluid with an almost insatiable appetite: the physiological equivalent of a black hole. General wisdom, repeated in our textbooks, was that a patient with an open belly needed at least 20 ml/kg/hr just to satisfy the “third space.”⁶ Liberal fluid administration was the fashion and liter upon liter of salt rich solutions were commonly poured into our patients. Edema was inevitable. The iatrogenic “Michelin Man,” eyes closed with peri-orbital edema, was routinely delivered to critical care units around the world. “Don’t worry—it does not harm—it’s just aesthetic.” “The beans (kidneys) will handle it.” “Nothing a few slugs of furosemide won’t fix.” These sounds and visions will be all too familiar to many readers. In 1967, Shires and Francis Moore (former professor and surgeon-in-chief, Harvard Medical School, Boston) wrote an article entitled “Moderation” in which they stated:⁷ “Salt solutions were undesirable during and after the operative period, unless there was external loss or traumatic edema. . . . The recommendation has been made by some that salt solutions should be used to ‘fill’ the vascular volume and then ‘maintain’ it by flooding the interstitial fluid volume. These advocates also advanced the idea that patients should be given four times the anticipated blood loss before it occurs. . . . The tendency of physicians and surgeons to go all out for new ideas, is noteworthy. . . . But it should be tempered with caution in adopting simple rules of thumb that prevent accuracy in estimates and replacement. . . . Instead of any such rule of thumb, the surgeon should carry on with his established habits of careful assessment of the patient’s situation, the losses incurred, and the physiologic needs in replacement. The objective of care is restoration to normal physiology and normal function of organs, with a normal blood volume, functional body water, and electrolytes. This can never be accomplished by inundation.”⁷

Nearly 50 years since this plea went out, the current observational cohort data suggest that inundation persists as a commonly deployed therapeutic approach and has been joined by a new

fashion—that of desiccation (or fluid restriction). A number of studies have explored the impact of so-called “fluid restriction.” Perhaps most notably in recent years, Brandstrup et al. demonstrated that “restriction” of peri-operative fluid volumes resulted in better outcomes in a multi-center European randomized clinical trial.⁸ Subsequent studies and meta-analyses have reinforced this view. It is not unusual in Enhanced Recovery after Surgery (ERAS) to find the term “intraoperative fluid restriction.”⁹ However, more detailed examination of the literature and more recent scholarly reviews offer alternate language: “zero balance” or the avoidance of salt and water excess.^{2,10} The advocates of “restriction” were responding to a world of inundation and wished for moderation. The intent was not to advocate actual restriction, just a brake on liberal or excessive administration of salt solutions. However, as Moore and Shires pointed out 50 years ago,⁷ many of us are dedicated followers of fashion, and have a tendency to go all out for the *new thing*, in this case fluid restriction. Sadly, it looks like the *new thing* is another “rule of thumb that may prevent accuracy in estimates and replacement” and may similarly be causing harm.^{3,7}

So why not just give the right amount of fluid guided by “careful assessment of the patient’s situation, the losses incurred, and the physiologic needs in replacement”?⁷ This is the mantra of the “optimisers” or “goal directors.”^{2,3,10-13} Why not use physiological measurements including advanced cardiac output monitoring to guide fluid therapy? Why not reduce the background “maintenance” infusion of balanced crystalloid to a much lower level, consistent with the true estimates of requirements available from modern scientific studies (approximately 1–3 ml/kg/hr) and only give additional boluses of fluid to match need judged by measured volumes lost and changes in hemodynamic variables.¹¹⁻¹⁵ On balance, the literature suggests that any algorithm-based perioperative fluid regimen results in improved patient outcomes, and the largest published randomized clinical trial demonstrates that lower volumes of fluid are administered in the intervention group, supporting the notion of “Goal-Directed Fluid Restriction.”¹⁰⁻¹¹

International audits of perioperative fluid management suggest that the availability of institutional guidelines, algorithms, audits, and the application of goal directed fluid management guided by flow monitors is rare.¹²⁻¹⁴ Clinical experience, blood pressure, central venous pressure, and urine output are the most commonly used guides.¹² When surveyed about poor adoption of “Goal Directed Therapy,” there are 3 recurring themes that emerge (in rank order): lack of availability of monitoring tools, lack of experience with instruments, and no perceived benefit.¹⁴ Regarding the evidence of perceived benefit, a recent meta-analysis concludes that there is no

See “Fluid Management,” Next Page



“We know that inappropriate fluid management in the perioperative period can cause harm, delayed recovery and complications for patients. The CHEERS

acronym is an aide-memoire that encapsulates those goals that fluid management should seek to meet, reflecting the principles of enhanced recovery. Clinicians should be ever mindful of the importance of giving the right amount of fluid.... not too much....not too little...

C.H.E.E.R.S.

Carbohydrate loaded (not hungry)
Hydrated (not thirsty)
Euvolemic (the right amount of fluid)
Eunatremic (the right amount of salt)
Ready to
Start to

DR.EA.M.

Drink
Eat and
Mobilise

As soon as possible, achieving this on the same day of surgery in many instances....”

<http://cheers-dream.com>

Cheers-Dream Campaign is Technology-Agnostic

“Fluid Management,” From Preceding Page

evidence of harm and clear evidence of benefit in terms of reduced complications and length of stay.¹¹ However, there is still a lack of definitive evidence from large, high-quality, multicenter trials with patient centered outcomes. International teams are trying to address this.^{10,16} However, absolute clarity is unlikely as fluid management is a highly complex intervention that is changing year by year. If we get a definitive result for elective open intra-abdominal surgery, then what about laparoscopic, or robotic, or emergency surgery, and so on with no end of questions in sight. In the interim, we should accept that perioperative fluid management is a major patient safety issue and do something pragmatic to reduce iatrogenic patient harm.

If we accept that the status quo is sub-optimal and may be causing significant patient harm, then what can we, as a community, do now? When surveyed, the vast majority (86.5%) of ASA respondents and 98.1% of ESA respondents felt that their current hemodynamic management could be improved.¹⁴ Consensus statements have been published from a broad range of constituencies and all agree on the big message being the avoidance of fluid underload and overload.^{2,12} However, this important signal seems lost in the noise of very public arguments over relatively “small-print” issues such as colloid or crystalloid, Ringers Lactate or Saline, monitor A or monitor B. This notion partially drove the impetus for the development of the *Cheers-Dream* campaign in May 2015 at the first American Society of Enhanced Recovery meeting in Washington, DC.¹⁷ Started by a group of perioperative fluid management enthusiasts frustrated by decades of lack of progress, the *Cheers-Dream* campaign concentrates on broad principles and objectives. The *Cheers-Dream* campaign is completely technology-agnostic and has no industry sponsorship. The aim of the campaign is quality improvement based on simple objectives, a patient centered outcome (the “DrEaM”), audit cycles, and ongoing education, and sharing of best practices. In other words, find out where you are, try to get to a better place and, if you get to a better place, please let others know how to get there.

In conclusion, current (chaotic) fluid administration is causing harm at the extreme of excess and inadequate fluid. Each of us can only know that we are not part of the problem if we engage in Quality Improvement on an on-going basis and can demonstrate consistency of practice and lack of harm (i.e., audit our fluid administration practice and outcomes). The *Cheers-Dream* campaign offers a clearly defined, easily measurable, and self-evidently patient relevant outcome variable for lack of harm, against which to compare your process variables

(how much fluid). If you can do this without a system, then great; if not, then please get a system that works for you—choose from the menu of options and get on and do it. So, cheers to the dream of moderation.

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Letter to the Editor:**Expert Clarifies Complexity of Unintended ICD Firing****To the Editor:**

We had a problem with an ICD a couple weeks ago that caught us by surprise. I thought it might be of interest to you and your readership.

The procedure was an open reduction and internal fixation (ORIF) of the left proximal humerus (essentially the shoulder) in the beach chair position. The anesthesiologist placed the magnet over the St Jude ICD in our usual manner (centered over the ICD). The ICD was in the left subclavian position, approximately 6 inches from the surgical field. The St Jude ICD does not emit a tone or vibration when the magnet has made contact, so there is no way to know for sure it is correctly placed.

Early into the case, during a long cautery run, the ICD fired, in spite of the fact that the patient did not have a shockable rhythm and the magnet was securely placed over the ICD. Upon investigation, we learned that the correct magnet placement to shut off the St Jude ICD is slightly different from almost all other ICD models. I say "almost all" because during my investigation, I learned that the Boston Scientific "EMBLEM" model has the same requirement.

For these models, the magnet should be placed such that the metal arc of the magnet is centered over the center of the ICD body, with the "donut hole" of the magnet slightly off center. I have been told that the arc emits more magnetic force than the center.

One excellent reference is the 2011 review article "Clinical Applications of Magnets on Cardiac Rhythm Management Devices" (our own Dr. Benzy Padanilam is a co-author).¹ Two things struck me during this investigation. First, not all of the St Jude representatives were aware of these suggestions of magnet placement. Second, there is no mention of this idiosyncrasy in the most recent (2011) HRS/ASA Consensus Statement on the Perioperative Management of Patients with ICDs/PMs.

Thank you.

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Reference

1. Jacob S, Panaich SS, Maheshwari R, Haddad JW, Padanilam BJ, John SK. *Europace*. 2011;13:1222-30.

Dear Dr. Addleman,

You presented an interesting case of a patient undergoing an ORIF of the left proximal humerus in the beach chair position with an ipsilateral St. Jude ICD generator that fired during a prolonged period of electrocautery. This case merits discussion to examine the possible causes of the ICD

firing inappropriately. By the term "firing inappropriately," I am referring to electromagnetic interference, such as electrocautery, which is interpreted by the ICD as a tachyarrhythmia meeting the threshold for tachyarrhythmia therapy, and subsequently delivering a calculated shock.

Assuming a device check revealed no malfunction of the ICD, the most likely reason the ICD delivered inappropriate anti-tachycardia therapy is the magnet lost contact with the ICD generator, regardless of whether the magnet was initially centered over the generator or off-center. With a humeral fracture in a patient with an ipsilateral ICD, the chest muscles around the generator are in continuity with the shoulder. Movement of skin or muscle overlying the generator during manipulation of the ipsilateral arm could result in the magnet losing contact with the ICD generator. The non-supine position further increases the likelihood of disengagement of the magnet with the ICD generator.

It wasn't noted in the report whether or not the magnet function was disabled in the patient's device. Some manufacturers allow the device to be programmed to not have a typical response to magnet placement. For St. Jude devices, the magnet response can be turned off, meaning magnet application will not suspend anti-tachycardia therapy. Therefore, a provider who wasn't aware that magnet function had been programmed "off" might place a magnet over the device thinking it would suspend tachyarrhythmia detection; however, when the magnet response is programmed "off," a magnet will not suspend tachyarrhythmia therapy. In order to determine if the magnet function has been disabled, the device must be either interrogated using a programmer, confirmed with the manufacturer's registry of devices, or confirmed with the physician who normally manages the patient's device.

Another factor in magnet engagement is patient size. The exact location of the ICD generator can be difficult to ascertain in a very obese patient with submuscular generator placement.

At times, even when the generator is located, a second magnet may need to be applied to the overlying skin to elicit the expected effect of the magnet on the ICD.

The initial central placement over the St. Jude device rather than off-center is probably the least likely cause of the ICD inappropriately firing in this case. A ring magnet is typically at least 90 gauss, whereas a field of greater than 5-10 gauss is considered sufficient magnet strength to affect device function. Although off-center magnet placement over a St. Jude device is recommended by the company documents, the strength of the manufacturers' ring magnet is sufficiently strong enough to ensure expected magnet functionality in most patients regardless of "center" versus "off center" placement. Engineers from other manufacturers who were consulted in preparation of this letter have also questioned the theory that "off center" placement gives significantly "better" magnetic field strength.

In patients with electrocautery occurring within 15 cm of the device and potential difficulties securing magnet engagement due to patient position, I would recommend arranging for device reprogramming to suspend tachyarrhythmia therapy during surgery. When that occurs, an alternative for external cardioversion/defibrillation should be immediately available, and the patient should remain on telemetry monitoring until the device is reprogrammed to its initial settings in the postoperative period.

Thank you for allowing me to contribute to the discussion.

Sincerely,

Annamarie Thompson, MD

Professor of Anesthesiology

Director, Anesthesiology Residency Program

Department of Anesthesiology

Division of Cardiothoracic Anesthesiology

Duke University Medical Center



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Distractions in the Anesthesia Work Environment: Impact on Patient Safety

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Save the Date

Wednesday, September 7, 2016

If you are interested in attending, please contact Dr. Stoelting (stoelting@apsf.org) for registration details.

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APSF Awards Two Safety Scientist Career Development Awards

by Robert K. Stoelting, MD

The Anesthesia Patient Safety Foundation (APSF) is pleased to announce the funding of 2 Safety Scientist Career Development Awards (SSCDA) starting July 1, 2016. The recipients of the awards are Amanda R. Burden, MD, and Ankeet D. Udani, MD, MEd. Their projects both involve a topic that is of increasing importance to the APSF—emergency manuals. This is evidenced by the September 2015 APSF experts' workshop titled: Implementing and Using Emergency Manuals and Checklists to Improve Patient Safety.

The chair of the review committee was APSF President Robert K. Stoelting, MD. Other members consisted of members of the APSF Executive Committee and a subset of members from the APSF Scientific Evaluation Committee. The SSCDA application requires that the investigator develop both a research plan and a mentoring/career development plan with the goal of developing the next generation of safety scientists. The award is \$75,000 per year for a period of 2 years (\$150,000 total).

A brief description of the SSCDA proposed projects and mentoring plans follows.



Amanda R. Burden, MD

Associate Professor of Anesthesiology
Director Clinical Skills and Simulation
Cooper Medical School of Rowan University
Cooper University Hospital

Dr. Burden's educational submission is entitled: "Emergency Manual Use: A Training Program for the Reader."

Background:

Omission of crucial steps in the treatment of patients during critical events is a threat to patient safety. Despite evidence that when Emergency Manuals (EMs) are used, teams more consistently adhere to guidelines and appropriately perform critical tasks, introduction and use of EMs and crisis resource management (CRM) education in health care remains inconsistent. While intense CRM education, training, and implementation processes have been adopted by other high hazard fields to assure

that EMs are used effectively, no standardized process exists in health care. In our prior work, we found that effective EM use is enhanced when a dedicated "reader" reads the EM to the team during critical events. Creation of a standardized program to educate, assess, and deploy trained "readers" stands to strengthen the implementation of the "reader" role and increase frequency of "reader deployment" in critical events.

Aims:

The primary aim of this project is to develop and evaluate a standardized EM Reader training program. The proposed project will use mixed methods to create, assess, and implement a standardized process of EM Reader and crisis management education to achieve accurate and consistent EM use by health care teams treating patients during critical events. The first phase includes an in-depth evaluation of current EM use and EM Reader needs in real and simulated perioperative emergencies to elicit key safety areas that will inform development of the course. Phase two includes creation of an educational program compatible with clinician needs and workflow elucidated in the initial evaluation phase and adapted from previously published implementation, assertiveness, and educational tools. Phase three involves implementation of the course and assessment of the process, and Phase four includes pilot deployment of trained "readers" to the clinical environment.

Implications:

This work has the potential to improve the safety of critically ill patients in the perioperative arena by helping assure that guidelines are followed through the use of EMs and by improving crisis management and teamwork skills to help health care teams work together more effectively.

Mentoring/Career Development Plan:

Dr. Burden will be mentored by David M. Gaba, MD (primary mentor); Steven K. Howard, MD; and Jeffrey B. Cooper, PhD (secondary mentors). Each brings significant expertise and unique abilities to assist Dr. Burden with the project and help her with the use of simulation to train interprofessional teams. She will pursue Masters level education in human factors, qualitative research methods, and medical education theory to assist in her efforts to create, implement, and assess this program. To gain additional education in human factors of EMs and CRM education, she will intern with Barbara Burian, PhD, Senior Research Scientist, NASA Ames Research Center and consultant to the Royal Aeronautical Society Flight Operations Group.



Ankeet D. Udani, MD, MEd

Assistant Professor of Anesthesiology
Department of Anesthesiology
Duke University

Dr. Udani's educational research submission is entitled "A comparison of two learning theories on emergency manual use: Classroom-based experiential learning versus electronic-based self-directed learning."

Background:

Humans perform poorly on cognitive and motor tasks during high-stress situations. The operating room can be loud, stressful, and present unexpected clinical surprises. In these crisis situations, emergency manuals can help anesthesia providers reduce reliance on memory, retrieve critical information, prioritize key actions, and avoid missing important steps. Similar manuals are used by other high-risk, high-reliability organizations to optimize safety. It is unknown how to teach anesthesia providers to effectively use emergency manuals in the operating room. We propose a comparative effectiveness study of classroom-based experiential learning versus electronic-based self-directed learning (E-learning) on anesthesia provider emergency manual use.

Aims:

The utility of emergency manuals is diminished when providers are unfamiliar with manual content. There is a need to study and optimize the process of teaching initial familiarity and use of emergency manuals. We will design, implement, and assess the impact of 2 exclusive, educational curricula. Our primary aim is to compare the impact of self-directed E-learning versus experiential learning methods on anesthesia residents' use of emergency manuals during simulated intraoperative crises. Our secondary aims are to determine the impact of the 2 distinct educational curricula on residents' knowledge, attitudes, and use of emergency manuals before, during, or after real intraoperative crises.

See "Awards," Next Page

Mentor Part of Career Development

“Awards,” From Preceding Page

Implications:

Our analysis will compare self-directed E-learning versus experiential learning. We will discover whether an innovative, self-directed E-curriculum is more effective in teaching emergency manual use than the current method of simulation-based, experiential learning. We will also assess the impact of the 2 curricula on emergency manual use by anesthesia trainees in the operating rooms. In line with the APSF’s mission, this project will allow us to systematically implement a new patient safety initiative, starting with effective training and education.

The findings from our proposed project will add important knowledge to the nascent field of emergency manual training, use, and implementation. Our efforts will focus next on how to train all operating room personnel (surgeons, nurses, technicians, etc.) efficiently and effectively to manage critical events best by using emergency manuals. And then, how to maintain best practices in perioperative crisis resource management. We will design, test, and implement effective training methods to eliminate error and optimize perioperative patient safety.

Based on results from this project, we will deliver the most effective curriculum’s educational resources to anesthesiology residency programs and the anesthesiology community at large. We will continue to assess the curricula for implementation success and long-term improvements in patient safety and trainee education.

Mentoring/Career Development Plan:

As part of this APSF award to train young safety scientists, Ankeet D. Udani, MD, MSEd, will be mentored by Jeffrey Taekman, MD. Dr. Udani has previously designed and studied the impact of educational strategies in anesthesiology. With this career development award, Dr. Udani will develop skills in implementation science to complement his knowledge in anesthesia education, simulation, and patient safety. Dr. Udani’s development through this award will give him the skills necessary to gain experience in translational research design in medical education. Dr. Udani aims to be a leader in thematic and systematic design of educational interventions to best impact perioperative patient safety at the level of clinical care and population outcomes.

HAI: When in Doubt, Blame Anesthesia. Could They Be Right?

by Ian Yuan, MD, and Jeffrey M. Feldman, MD, MSE

Two patients come into a hospital for elective knee replacements. Their surgeries are uneventful, but both are found to have surgical site infections in follow-up visits. In the first patient, the anesthesia professional forgets to give antibiotics prior to the start of the procedure. The second patient gets pre-incision antibiotics, but the anesthesia professional uses an open stopcock for repeat medication injections during surgery. What role, if any, did the anesthesia professional play in the postoperative infection?

Fortunately, the first scenario is increasingly rare, due to heightened awareness and accountability stemming from national quality improvement projects, such as the Surgical Care Improvement Project that mandates administering indicated antibiotics within one hour of incision. The second scenario, however, is a common occurrence and highlights the challenges anesthesia professionals face as we seek to eliminate our role in health care-associated infections (HAIs). Although there have been significant decreases in HAIs over the past few years (46% decrease in central line-associated bloodstream infections and 19% decrease in surgical site infections¹), an estimated 4% of inpatients are still affected by HAIs during their admission.² HAIs are considered preventable and constitute serious safety and economic concerns, with an annual estimated cost between \$28.4 and \$33.8 billion.³ With recent changes in hospital reimbursement, treatment for many HAIs are no longer reimbursed and occurrences of HAIs may even invoke a financial penalty to the providers.⁴ This economic disincentive should stimulate clinicians and health care administrators to take an even more aggressive approach to preventing HAIs.

Anesthesia professionals can and should play an active role in the prevention of HAIs. While we have taken responsibility for timely administration of antibiotics and have reliably accomplished this goal, it is apparent that our role in preventing HAIs goes well beyond these measures. We are in frequent contact with the patient’s skin and mucosa and, more importantly, we repeatedly access the bloodstream while administering medications, fluids, and obtaining blood samples.⁵ Studies have found anesthesia professionals to have the lowest compliance with hand hygiene recommendations across all medical specialties,⁶ and that our hands are frequently contaminated with major bacterial pathogens even prior to patient contact.⁷ This contamination serves as a significant source of anesthesia work environment (AWE) and stopcock contamination.^{7,8} Recently, using bacterial phenotype and pulsed-field gel electrophoresis analysis, researchers from the

Dartmouth group have shown that transmission of bacteria, including vancomycin-resistant enterococci, to IV stopcocks occurs frequently (32%) and early (< 5 minutes), and that higher levels of bacterial contamination are associated with higher rates of intravenous stopcock contamination, and possibly increased patient mortality (P=0.0395).^{8,9}

Despite growing evidence that contaminated IV stopcocks can lead to HAIs, very few procedural changes have been implemented. There are several barriers towards reducing the contamination of the IV injection port that need to be overcome in order to reduce anesthesia-associated HAIs. First, the consequence of a contaminated injection port may not manifest itself until the patient develops a blood stream infection several days later, when they are no longer under our care. This delay, coupled with our inability to detect the culprit, makes it hard to obtain real-time feedback when the port has been contaminated. Thus, it is difficult for us to modify our behavior accordingly, whether at the time of contamination or generally in our protocols generating contamination. Second, in a typical general anesthesia procedure there are up to 60 opportunities for hand hygiene,¹⁰ even though the typical anesthesia provider performs hand hygiene less than once per hour during a procedure.¹¹ During critical portions of anesthetic care, such as induction and emergence, the frequency of tasks performed makes it even harder to comply with hand hygiene recommendations. Not surprisingly, these 2 moments are associated with the highest rate of contamination of the AWE.¹² Furthermore, unlike documenting antibiotic administration compliance, it would be nearly impossible to document every single opportunity for hand hygiene or scrubbing of the stopcock, making it hard to track and improve compliance of these decontamination efforts. We are therefore dependent on the habits of the individual provider, which leads to the last barrier—the culture of the practice. The collective habits of individuals working in the group shape the practice culture and these habits may be resistant to change. It typically requires more than one person to change a group’s practice, often coupled with efforts to enforce compliance with anesthesia infection reduction interventions.

Although the problem of addressing our potential role in HAIs is complex and challenging, it is possible to develop habits that can make a difference. One intervention to address hand hygiene involved placing hand-washing gels in easily accessible areas of the AWE, which in one

See “HAIs,” Next Page

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Best Practices Need to Be Identified to Minimize HAI

“HAIs,” From Preceding Page

study showed a 27-fold increase in hourly hand decontamination events leading to reduced bacterial transmission of stopcock sets, reduced AWE contamination, and ultimately reduced 30-day postoperative HAI.¹¹ To decrease the contamination of IV injection ports, one hospital successfully implemented a medication manifold system that was kept away from the patient and only touched with clean hands after hand hygiene.¹³ This significantly reduced the incidence of blood stream infections in ICU patients who had traveled to the operating room for procedures from 14.1 per thousand trips to 0. Interventions intended to decrease contamination of the AWE include creating clearly demarcated areas for clean and contaminated items, defining work areas for “next case” preparation to minimize co-mingling current and future case supplies, defining policies on when unused items should be returned to storage, addressing the problem of keyboard/knob/drawer contamination, and working with anesthesia technicians to define best practices on cleaning the AWE between cases.¹⁴ Vendors can also play a role by designing equipment with contamination resistant materials and surfaces that are easy to clean. Still, more research is needed to address the “best” way to clean and prevent cross-contamination of the AWE. In order to sustain the practice changes associated with these interventions, leadership needs to be committed and provide resources, including frequent monitoring and feedback to the provider.

There is little doubt that the causes of surgical HAIs are numerous and involve many other health care professionals. Just because other professionals also contribute to HAIs does not mean that we should absolve ourselves of responsibility and resist additional rules and regulations governing anesthesia practice intended to reduce HAIs. The evidence suggests that anesthesia professionals contribute to the risk of HAIs in the perioperative setting and can play a role in reducing that risk. What is not clear are the best practices and technologies required to eliminate our role in HAIs. As the foremost organization on patient safety in the perioperative period, the Anesthesia Patient Safety Foundation should take the lead in tackling the barriers to eliminating the role of the anesthesia professional in HAIs through education, research, defining best practices, and aiding the appropriate organizations for implementation of policy.

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Dear SIRS

Why Do the Gauss Lines Matter?

S I R S

AFETY
INFORMATION
RESPONSE
SYSTEM

Dear SIRS refers to the Safety Information Response System. 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. This process was developed by Dr. Michael Olympio, former chair of the Committee on Technology, and Dr. Robert Morell, co-editor of this newsletter. Dear SIRS made its debut in the Spring 2004 issue. Dr. A William Paulsen, current chair of the Committee on Technology, is overseeing the column and coordinating the readers' inquiries and the responses from industry.

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.

Dear SIRS:

Anesthesia equipment within the MRI suite is exposed to powerful static, gradient (pulsed), and radiofrequency electromagnetic fields.¹⁻³ We describe the potentially lethal failure of an Aestiva MRI anesthesia ventilator (Aestiva/5 MRI, Datex-Ohmeda, General Electric (GE) Healthcare Madison, WI) within the confines of a 1.5 Tesla (T) MRI suite. During the preparation for a pediatric general anesthetic, the ventilator maintained more than 30 cmH₂O of PEEP while in the pressure-controlled ventilation mode when PEEP was activated. "Sustained pressure" and "check flow sensor" alarms were appropriately triggered. Manual ventilation was able to be performed without expiratory obstruction or sustained expiratory pressure, and the manual adjustable pressure level valve functioned correctly. The machine was removed from service and no patient harm occurred. The ventilator malfunction was completely reproducible and sustained in a controlled environment distant from the magnetic field. GE technical support determined that the flow control valve required recalibration. The company stated that they had not encountered this malfunction previously.

Further inspection of the machine also revealed absence of a built-in side bar designed to prevent the integrated ventilation system from swinging laterally. Consequently, the electronic ventilator system was able to swing outside the footprint of the machine, into the 300 gauss zone, without triggering the built-in gauss indicator which is remote from the ventilator system. The machine's flow control valve, computer processing unit, and side bar were all replaced. The machine passed a full inspection and was put back in service. Our other Aestiva MRI machines were fully inspected after this event. The manufacturer recommended no further action for these machines other than regularly scheduled inspections and maintaining them outside 300 gauss. An FDA/Medsun report was submitted following this incident. After a failure mode and effects analysis (FMEA), permanent 300 Gauss line markers were installed in all MRI suites.

Indications for pediatric MRI are increasing due to the absence of ionizing radiation, high image resolution, and capability for function or biochemical measure acquisitions in real time. Infants and children undergoing MRI frequently require general anesthesia with intubation and mechanical ventilation due to patient condition or to eliminate respiratory artifact, by inducing prolonged periods of apnea.

The magnetic field strength inside MRI Zones 3 or 4 present significant challenges to biomedical equipment. There is no standard definition of MRI compatibility, and sensitive internal components of MRI-compatible equipment may be degraded by acute or chronic exposure to high-gauss magnetic fields. In this case, we suspect that repeated exposure to greater than 300 gauss interfered with ventilator performance resulting in patient risk. Permanent gauss line markers help mitigate this risk by providing visual cues against an invisible threat. However, there remain many barriers to the delivery of safe anesthesia care within the MRI suite including noise, field avoidance, obstructed lines of sight, and projectile risk.^{1,2} The advent of 3T MRI presents new challenges associated with stronger magnetic fields. The American Society of Anesthesiologists has published multiple practice advisories for the provision of anesthetic care during magnetic resonance imaging.^{1,2} It is imperative that anesthesiologists, nurse anesthetists, and anesthesiologist assistants understand MRI associated risks and remain vigilant.

*John P. Scott, MD, Assistant Professor
George M. Hoffman, MD, Professor
and Richard J. Berens, MD, Professor*

*Medical College of Wisconsin, Departments of
Anesthesiology and Pediatrics, Sections of Pediatric
Anesthesia and Pediatric Critical Care.*

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Response from GE Healthcare:

Dear Drs. Scott, Hoffman, and Berens,

Thank you very much for reminding everyone of 2 important issues which are critical to maintain safe operation of medical devices, particularly in the challenging MRI environment.

1. It is important to ensure that equipment is maintained in its original configuration with all
See "Dear SIRS," Next Page

Dear SIRS

“Dear SIRS,” From Preceding Page

parts and components intact. Parts, such as the side bar, that you mention may seem to be unrelated to the safe operation of the device, but in fact these components are generally there for a reason and do need to be maintained in their original configuration. Your example illustrates this very clearly. This reminder applies equally to equipment used both within and outside of the MRI environment.

- Equipment designed for use in the MRI environment will include instructions and labeling describing how and where it may be

used within that environment. Your initiative to provide visual markers at the 300 gauss line is a good example that will help to ensure that equipment is used within specifications.

Once again thank you for providing this information.

Sincerely,

Kevin Tissot

Chief Engineer

Anesthesia and Respiratory Care

GE Healthcare

Editorial Note:

The American College of Radiologists have identified and labeled 4 zones within the MRI suite. Zone 1 is a “safe” area where gauss fields are typically less than 0.5 gauss, and is an uncontrolled area, accessible to the general public without any screening for ferromagnetic objects. Zone 2 is a buffer area between zone 1 and the hazards of zone 3 and 4. Typically screening of individuals occurs in zone 2 before being allowed into zone 3 or 4. Zone 3 is usually the area just outside the magnet room where the magnetic field is strong enough to present hazards to unscreened individuals. Zone 4 is the magnet room itself where the magnetic fields are strongest and from which ferromagnetic objects must be excluded.

Safety Issues With Gas Scavenging System in GE Avance and GE Aespire Anesthesia Machines

Dear Sirs:

An ASA 3 patient undergoing a cochlear implant procedure underwent induction of anesthesia and intubation without incident. The OR table was rotated 180 degrees to facilitate surgery. However, the anesthesia gas machine started alarming “PEEP High /Blockage?” Mechanical ventilation was stopped and hand ventilation initiated and the patient was found to have normal lung compliance. No kinks or obstructions were identified in the ventilator tubing or endotracheal tube, and suctioning of the endotracheal tube was unremarkable. Subsequently, it was noted that the scavenger bag was full despite the needle valve being almost completely open. The scavenging bag was removed, allowing waste gases to release into the OR and decreasing the PEEP to normal. It was then noted that the evacuation pipeline became dislodged from the attachment to the bottom of the machine. It was reconnected, and the alarm message and audible alarms resolved.

Shashank Saxena, MD, is Clinical Assistant Professor at the University of Pittsburgh School of Medicine and Staff Anesthesiologist, VA Pittsburgh Health Care System, Pittsburgh, PA.

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Michael P Mangione, MD is Associate Professor at the University of Pittsburgh School of Medicine and Chief of Anesthesia, VA Pittsburgh Health Care System, Pittsburgh, PA.

GE Healthcare Response

The gas scavenging 10 cmH₂O positive pressure relief valve within the Advanced Breathing System of Aespire, Avance, and Aisys anesthesia systems was designed in 2000 to comply with 2 standards: EN 740:1999 Anaesthetic workstations

and their modules—Particular requirements; and ISO 8835-3:1997 Inhalational anaesthesia systems—Part 3: Anaesthetic gas scavenging systems—Transfer and receiving systems. Clause 111.1.2c of EN 740:1999 requires the pressure rise at the patient connection port of a breathing system shall not exceed 1 kPa (10 cm H₂O) at a continuous flow of 75 L/min under single fault conditions, and Clause 4.2.1 of ISO 8835-3:1997 requires the pressure rise at the inlet of the AGSS shall not exceed 1.5 kPa (15 cmH₂O) at a flowrate of 75 L/min, having introduced single faults one at a time.

There are multiple Anesthesia Gas Scavenging System (AGSS) options for the Aespire, Avance, and Aisys. The 2 most common options are the high vacuum active AGSS with adjustable flow and the high vacuum active AGSS with low flow. The high vacuum active AGSS with adjustable flow is a closed system with a needle valve and a waste gas reservoir bag.

If the Aespire, Avance, or Aisys closed system AGSS becomes occluded or if the hospital vacuum source is lost, back pressure will build in the anesthesia system and expand the waste gas reservoir bag until gas is relieved to atmosphere by the 10 cmH₂O positive pressure relief valve. The anesthesia system will announce a high priority alarm, “PEEP high. Blockage?” when an elevated pressure is sustained for 15 seconds. The threshold for the sustained airway pressure alarm depends on the PEEP setting and the airway pressure high limit (Pmax) alarm setting. The default sustained airway pressure threshold during mechanical ventilation is 8 cmH₂O when Pmax is 40 cmH₂O and PEEP is Off. The default threshold will allow the “PEEP high. Blockage?” alarm to occur before waste gas is relieved to atmosphere. The clinician can identify an AGSS blockage or a loss of vacuum to the AGSS by seeing the fully inflated waste gas reservoir bag.

Prior to Aespire, Avance, and Aisys, the Aestiva anesthesia machine was designed with a similar 10 cmH₂O positive pressure relief valve; however, the Aestiva relief valve is within the integrated AGSS. The Aestiva closed system AGSS option differs from Aespire, Avance, and Aisys by requiring an external add-on kit with the needle valve and waste gas reservoir bag. The add-on scavenging kit contains a positive pressure relief valve specified to relieve at 4.5–7 cmH₂O at a flow of 60 L/min. However, if an occlusion were to occur in the Aestiva AGSS or between the Aestiva AGSS and the add-on scavenging kit, back pressure will build in the Aestiva until gas is relieved to atmosphere by the 10 cmH₂O positive pressure relief valve.

As an alternative to the closed system AGSS, there are open system AGSS options for the Aespire, Avance, and Aisys that do not build back pressure in the anesthesia system if there is insufficient extraction flow. The open system manages peak waste gas flow that exceeds the extraction flow by using a 2 L holding volume within the Advanced Breathing System. Waste gas will spill from the holding volume into the room only if the waste gas flow exceeds the extraction flow for an extended period of time. When extraction flow exceeds the waste gas flow, the extraction will remove waste gas from the holding volume. Since the open system AGSS is designed for the average extraction flow to exceed the average waste gas flow, the hospital vacuum source will entrain room air.

No matter which scavenging system you use, we thank you for bringing attention to the importance of verifying correct operation of the scavenging system prior to each use.

Sincerely,

Karl Knauf

Lead System Designer

GE Healthcare

A Japanese Perspective on Patient Safety

by Katsuyuki Miyasaka, MD, PhD, FAAP

Anesthesia patient safety is a primary common concern of anesthesia providers all over the world. Yet my experience in academic institutions both in Japan and in North America has shown me there are distinct differences in the culture of clinical anesthesia, despite each region's sharing the same sets of scientific evidence and similar procedures in everyday anesthesia care.

The history of Japanese anesthesia dates back to 1804, some 40 years before Morton's Ether Dome event (1846).¹ Seishyu Hanaoka (1760-1835) provided general anesthesia for breast cancer using datura extracts. However, modern Japanese anesthesia started in 1950 when Dr. Meyer Saklad (1901-1979), director of the department of anesthesiology at Rhode Island Hospital (Brown University), introduced the concept of anesthesiology into Japan. Dr. Saklad was a member of the Unitarian Service Committee Medical Mission, which was a part of the US occupation mission.² At the time, anesthesia was provided mostly by junior surgeons in Japan. The mission contributed to academics by donating several textbooks that laid the basics for the study of anesthesiology in Japan and inspiring young physicians to study in the US. The nation's first anesthesia department was established in 1952 at the University of Tokyo. Professor Hideo Yamamura (born 1920), who studied at SUNY, Albany, was appointed as the first head of the department. Therefore, Japanese anesthesiology, unlike other medical specialties which were influenced mainly by the German medical system, was strongly influenced by American medicine.¹

Japan faced a critical health care crisis when WWII ended in 1945, as most major cities and daily life had been totally demolished, resulting in severe poverty and food shortages.¹ Efforts by US occupational forces helped restore and establish a democratic society and public health. Japan attained a rapid improvement in health statistics (increased life expectancy 14 years between 1947 and 1955). Japan was able to introduce universal health coverage in 1961, long before rapid economic growth followed. The system is claimed to be responsible for the rapid attainment of its current excellent health care status, such as the longest longevity and lowest infant mortality in the world.¹

The Japanese health care system is socialistic in that it is designed to provide equal access to health care with a universal fee schedule for all. This government-controlled system worked extremely well when the focus was mostly on curing diseases or decreasing mortality. As the economy grew and people started taking the medical system for granted, expectations also grew for perfect medical practice (zero fault) with the best

possible quality. Physicians could now be blamed by patients if the outcome was not optimal, even though the physicians' practice is controlled and restricted by the fee schedule.³

Two consecutive high-profile medical mishaps occurred in two major teaching hospitals in 1999, resulting in social distrust of the medical community. In one case, accidental injection of an antiseptic liquid instead of antibiotics caused a patient's death.³ The 2 nurses and 1 physician involved were charged with professional misconduct. The president of the hospital was charged with not reporting the incident to the police soon enough (within 24 hours). False accusations by the media of a cover-up by the hospital staff and related gossip caused social turbulence. In the other case, accidental swapping of an open heart and a lung resection case occurred in the OR and resulted in 2 wrong-site surgeries. The cardiac surgeon, a thoracic surgeon, and 2 anesthesiologists, including one who noticed signs of the error, but could not stop the wrong surgeries, and 2 nurses were criminally charged.³

Significant changes were introduced into medical practice after these incidents. Ironically, the perceived value of anesthesia services increased, and the suboptimal practice of surgeons providing anesthesia by themselves while performing surgery rapidly decreased. While this change was welcomed by anesthesiologists, the increased need for anesthesia providers was not fully addressed.

Another more serious change was that society demanded that physicians report any unexpected in-hospital deaths to the police. This meant even medically explainable death became subject to criminal investigation. Anesthesiologists are at high risk as they are constantly dealing with life threatening situations. The conviction rate in Japan is extremely high (99.8%), and therefore, it is not only stressful, but frightening to innocent physicians involved, since they risk losing their medical license at any level of criminal charge. It is also very counter-productive from the point of view of preventing recurrence, as the main interest of Japanese law enforcement is to seek out and prosecute any wrongdoing. Punishing doctors will not improve patient safety if any well intended debriefings are interpreted the same way as manslaughter confessions. In fact, a significant number of anesthesiologists have suffered from impairment of medical practice, have been forced to change their careers, quit working, or even commit suicide.

Medical malpractice lawsuits continued to increase until another striking incident happened in 2006. An obstetric/gynecologic surgeon was arrested on a charge of professional negligence resulting in a case of fatality (from massive bleed-

ing during a caesarian section due to placenta previa and accreta). However, the surgeon was found not guilty in 2008 after nearly 2.5 years of intense legal battles. Fear of litigation produced a nationwide shortage of obstetricians. It was fortunate that medical malpractice lawsuits started to decrease overall after the settlement of this trial.³

In October 2015, after years of debate, Japan introduced a new medical accident investigation system which is aimed at preventing recurrences rather than pursuing individual responsibility or prosecuting health care workers.⁴ World Health Organization guidelines centered on non-punishment, confidentiality, and independence are referenced.⁵ The good news is that administrators are now not forced or rushed to report unexpected hospital deaths during medical care to the police unless the hospital deems it is a criminal case. It is too early to conclude whether the new system will work as expected, but it is definitely a big step forward to reducing our fear of facing unjustified criminal charges for less than optimal outcomes, and in the absence of negligence.

According to the 2015 report of the Japanese Ministry of Health,⁶ an estimated 2,700,000 cases of general anesthesia were given in Japan, which is a substantially small number compared to the estimated 25,000,000 cases or more in the US. Considering the fact that the population of Japan (127,000,000) is about 40% of the US (314,000,000), a mere 1/4 of general anesthesia cases are given per capita in Japan.⁶ Social and cultural differences definitely play a role, but equally or even more significant is the relatively small number of anesthesiologists in Japan and limited support by allied health care providers, such as nurses and pharmacists for activities outside the operating room (OR). As a result, anesthesiologists are rarely involved in procedural sedation services or acute pain services. Very few epidurals for labor analgesia are performed in Japan.

The majority of anesthesia care is provided by trained physician anesthesiologists in Japan. There are no nurse anesthetists (CRNAs) as only physicians are legally allowed to administer anesthesia. Although specialty training in anesthesiology and a board system exist, legally any physician can administer and bill for anesthesia with only a small difference in fees.

While an estimated 20% of anesthesia cases are still handled by surgeons, many more cases of so-called "anesthesia" or sedation are performed by non-anesthesiologists without any anesthesia supervision. Examples of where non-anesthesia providers deliver sedation include endoscopic procedures, interventional cardiac procedures,

See "Japan," Next Page

JSA and ASA Share Many Similar Safety Standards

“Japan,” From Preceding Page

and pediatric MRI studies. Same day surgery cases are increasing, but they are based on hospital practice and there are very few stand-alone surgical centers. Thus, most anesthesia is provided in hospital based ORs with backup beds and other medical services, contributing to anesthesia safety.

A new system for perianesthesia nursing, in which specially educated (master’s degree) nurses exclusively support and assist anesthesiologists throughout the entire perioperative period, both in and out of the OR, is being developed.⁷ They will be strong allies to anesthesia services, especially anesthesia services outside of the OR, but their number is still small. Most professional anesthesiologists and their trainees belong to the Japanese Society of Anesthesiologists (JSA) with a membership of 12,240 as of March 2016.¹

The JSA started a voluntary annual perioperative mortality and morbidity survey in 1992 among JSA approved anesthesia training hospitals (approximately 800 hospitals).^{8,9} The latest interim unofficial data available (2009-2011) encompasses 4,401,910 reported general anesthesia cases, including 5,353 cases of critical perioperative morbidity, indicating a rate of 3.93/10,000 deaths in the perioperative (within 30 days of anesthesia) period. This is significantly lower (better) than that of 5.51/10,000 in the previous 5-year period (2004-2008).^{8,9}

Anesthesia was responsible for perioperative death in 32 cases, indicating an anesthesia mortality rate of 0.07/10,000, a continuing falling trend from previous years. Causes of death in the latest survey were drug related (6), aspiration (5), ventilation related (5), overdose of the main anesthetic agent (4), and inappropriate fluid/transfusion management (3). There was one reported case of death from anesthesia due to airway management at induction of anesthesia (0.002/10,000). The results of this survey are limited by the following: its reliance on voluntary reporting, its coverage of only cases carried out by professional anesthesiologists, the unknown quality of individual reported data, and a rather long follow-up period of 30 days following anesthesia. Still, it is a very unique and meaningful activity of the JSA to help us recognize the importance of anesthesia safety.^{8,9}

JSA guidelines (last revised in 2014) and ASA guidelines (last affirmed in 2015) share almost identical standards for basic monitoring, except the ASA extends their scope to procedural sedation, such as the recommendation for capnometry in non-intubated patients, which is still not clearly established in JSA guidelines.⁷⁻⁹

Japanese anesthesiologists frequently refer to textbooks by Miller (translated into Japanese) or Smith, use mostly US or European made anesthesia machines, and frequently perform ultrasound guided regional nerve blocks. However, they have a preference for using sevoflurane, propofol by total continuous infusion, and hydroxyethyl starch (HES) (6% HES 130/0.4 in 0.9% NaCl). The use of electronic anesthesia recording systems is widespread in Japan, with adoption estimated to be around 70% in anesthesia training hospitals with over 300 beds. The practice of confirming monitored data by handwriting has largely vanished, but tracking of non-electronic data such as information obtained by precordial stethoscope or physical contact to the patient has also faded. I feel this is a concern for anesthesia safety. The availability of pharmaceuticals and medical equipment plays an important role in anesthesia practice, but some differences reflect differences in health care insurance systems where physicians may not be sensitive enough to the cost of care. Japanese anesthesiologists probably use more sugammadex than in any other country.¹⁰

As Japanese surgeons and hospital administrators wish to increase revenue by increasing the number of surgeries, the demand for anesthesia services is steadily rising. Our priority is always patient safety. In addition to securing patient safety and comfort in the OR, we should work hard to extend our services outside of the OR to promote a culture of safety.

Dr. Katsuyuki Miyasaka, MD, PhD, FAAP, is a designated professor of Perianesthesia Nursing at St. Luke’s International University, Tokyo, Japan. He

claims no relevant financial relationships to disclose regarding this review.

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Developing Patient Safety Leaders: Leadership Fellows Share Insights Gained from Program

by Charles E. Cowles, Jr., MD, MBA; Maria van Pelt, PhD, CRNA; Sorin J. Brull, MD; and John H. Eichhorn, MD

Encouraging, promoting, and supporting the development of current and future leaders in patient safety activities is one of the important missions of the Anesthesia Patient Safety Foundation. A significant element of this effort has been the APSF sponsorship of participants in a fellowship program for the training and development of leaders in patient safety. That fellowship program was organized by the Health Research & Educational Trust (HRET) under the joint sponsorship of the American Hospital Association (AHA) and the National Patient Safety Foundation (NPSF). This article includes reflections on that experience in years past and also the general concept of patient safety leadership development from 4 APSF-affiliated fellowship participants.

Leading the Way in Patient Safety

By Charles E. Cowles, Jr., MD, MBA (2014-15)

As the most recent recipient of the Ellison C. "Jeep" Pierce Scholarship for the Comprehensive Patient Safety Leadership Fellowship of the AHA/NPSF, I offer a summary of effective strategies for becoming a leader in patient safety. In doing so, I hope to foster the interest that others may have in this developing field. One of the best ways to start would be to quote Dr. Pierce, when he eloquently stated, "Patient safety is not a fad. It is not a preoccupation of the past. It is not an objective that has been fulfilled or a reflection of a problem that has been solved. Patient safety is an ongoing necessity. It must be sustained by research, training, and daily application in the workplace."¹ The goal in patient safety efforts should be to prevent harm to our future patients, not simply reviewing incidents, which have already occurred.

Among many things learned in the leadership fellowship was a broad perspective on the basic concepts of patient safety. A logical way to organize patient safety efforts can be to break them down to the categories of people, processes, and product. Several types of people are stakeholders in patient safety. First and foremost is the patient; after all, the patient has the most to gain from a safe medical experience and, of course, the most to lose. Patients must be involved in the safety process; for instance, hospital patient safety committees should have patient representatives. Patients often give a unique perspective quite different from those of clinicians. Patients and their families can also become engaged in the safety process. One hospital executive told me that when his wife was in the hospital, the hand hygiene compliance rate was 100%. This was due to his asking everyone who came into the room if they had washed their hands and if not, to please do so. It was not

because of training, policy, or even his leadership position. Surgical patients can be given a set of questions on a card that prompts them to ask questions such as, "Will you use a surgical checklist before my surgery?" or, "What is the plan for antibiotics?" Patients or families can also become a voice after a medical error. For instance, they can participate in the root cause analysis (RCA). Nothing is a more compelling story than listening to the patients relate what happened during their care. Patients want their providers to get the message that mistakes made should not happen again. Involving patients in the improvement process allows them to tell their stories and see first-hand that improvements are made.

Providers are other key stakeholders in patient safety. They should blend knowledge, experience, teamwork, and technology to create a maximally safe environment for patients. Knowledge can be maintained by keeping up with the latest professional guidelines for evidence-based practice, participating in courses and classes that focus on patient safety, or even by obtaining one of the many types of certification in patient safety offered by various national organizations. Experience may improve patient safety via the reporting of threats to the safety, whether by institutional incident reporting systems or by departmental conference presentations. Experience does not have to be at the expense of real patients; simulations and drills should be used to refine skills and identify opportunities for improvement.

Providers must incorporate others in their efforts and foster teamwork. Effective teams have a clear leader, clear goals, a cause greater than themselves, willingness to fight, standards of excellence, and team members who actually can interact with mutual respect. Providers should also "keep up with the times." We must constantly explore new technology, which supports safer care for the patient. Modern communication devices can allow us access to nearly unlimited information and puts references at our fingertips. However, this technology can also become a distraction if not used strategically and at appropriate times. Advances in artificial reasoning and intelligence can analyze data presented either by direct entry or even with image acquisition. For example, analytical software can detect several subclinical changes in vital signs and other measured clinical variables and subsequently alert clinicians to impending shock or respiratory failure well before it is evident to the human provider. Safe practitioners should critically appraise this technology and embrace useful devices and not hide behind the concept of "that is how we have always done things."

Leadership

We need safety leaders to lead by example. We also need facilities and institutions to support endeavors in patient safety. It is the most important core value within any health care practice. Executives should stand behind employees who chose safety over taking the easy way or cutting corners (particularly in the name of cost-savings). Managers should reinforce sound decisions and examine cases where unsafe practices and resulting near misses arise. Academic institutions should lead by factoring in formal efforts in patient safety by faculty as promotion criteria. Leaders should be chosen based upon how they foster the safety culture.

Process

Processes should be developed to decrease or eliminate opportunities for human error to be introduced (preventing the alignment of the holes in James Reason's Swiss cheese model).² Many times root cause analysis outcomes suggest further training of personnel or the development of policies and training sessions, but these are seldom effective. In all likelihood, the only effective means of prevention is to design products and use "smart" devices that help prevent the creep of human error. Error proofing by engineering and design is a concept used in other high reliability organizations, which could easily be incorporated into the practice of medicine and nursing.²

Best practices should not be kept as proprietary trade secrets, but rather shared for the benefit of all patients everywhere. Safe practices usually become the most cost effective and efficient manner of doing things. As an example, a simple pre-incision time-out can identify issues such as availability of instruments and blood products and anticipated complications; this simple step can reduce non-productive surgical time. These pauses in relevant cases can also identify issues such as the presence of high risk for a surgical fire and the plans to mitigate such a situation

Product

One of my mentors told me once: "You are only as good as your last anesthetic given." Current business trends are certainly reinforcing that statement. Most of us are using *TripAdvisor* or similar sites to review travelers' experiences with hotels and resorts; Yelp and Chowhound let us know what others have experienced in helping make restaurant-dining decisions. Consumers of health care are from the same population. Now care providers can plug their own name or facility into a search engine and instantly find sites that rate them based on patients' experience. Blogs are

See "Leaders," Next Page

Professional Interactions Present Educational Opportunity

“Leaders,” From Preceding Page

commonplace among those with chronic diseases, and they will name providers with whom they are satisfied (or dissatisfied). Government agencies and accreditors are maintaining searchable databases to catalogue outcomes information. We should seek out those who are highly rated and see what they are doing and see if we can replicate or even improve their methods of care delivery. Everyone knows the professionals we personally see or to whom we refer our family members. It is time to critically examine what makes those folks different. What is it exactly that make us believe they are highly qualified and safe practitioners? Professional societies promulgate guidelines and practice advisories to guide us on the safest manner of care and, although there maybe the few patients whose care doesn't quite fit the guideline, for the most part these protocols can be used as a routine and efficient way to practice anesthesia care.

Finally, I never set out with a goal in life to be a leader in patient safety. However, I learned that by always choosing the safer way to approach patient care and leading by example, co-workers and even administrative leaders will seek you out for solutions to safety issues. Being a patient safety leader is not a title, but rather a mindset for how you take care of patients, interact with others, and teach by example.

Additional Aspects Added

by Maria van Pelt, PhD, CRNA (2013-2014)

In spite of best patient safety efforts, the seminal Institute of Medicine report from 1999, “To Err is Human,” reported that as many as 98,000 U.S. patient deaths annually could be attributed to medical error.³ With improved event reporting and transparency, this estimate of catastrophic harm has recently been increased to greater than 200,000 U.S. annual patient deaths.⁴ The magnitude of the numbers reported defies comprehension and becomes impersonal; however, every death represents a personal patient safety “story.” Every one of these patient safety “stories” are multifaceted, and all too often the resultant emotional harm not only touches the affected patients and family members but also the involved caregivers and organizations at-large. In addition to the impact that catastrophic adverse events have on patients and families, the impact that these events have on providers and their ability to provide safe care in the aftermath has only recently been recognized.

While it is essential for patient safety leaders to employ effective strategies and tactics to improve patient safety and prevent future patient harm, the Patient Safety Leadership Fellowship impressed upon me the need for patient safety leaders to also implement support initiatives when these preventive patient safety measures fail. Research has

increasingly demonstrated the scarcity of formal organizational support programs available to impacted care providers after adverse events, and the potential risk that this gap poses in enabling them to return to their emotional and functional baseline of providing safe patient care.

The availability of support services and the provision of a support venue that is safe and accessible are essential for those who are accustomed to working in a culture that retains strong elements of autonomy and individual blame. Implementing a peer support program, where care providers are trained to provide “emotional first aid” to colleagues impacted by adverse patient events, can serve as an important entry point into a more comprehensive organizational support response. Patient safety leaders must leverage their skills and their understanding of organizational dynamics, system-based improvement, and human emotion to create this needed support. Combined with a strong commitment to the prevention of harm, enabling a supportive environment at the sharp end of care, particularly in the aftermath of a catastrophic event, provides a holistic patient safety approach, which is a critical step in the ongoing transformation of health care.

Defining and Extracting Patient Safety

by Sorin J. Brull, MD, FCARCSI (Hon) (2012-13)

For a long time, I had a difficult time defining what “patient safety” really was. With all due respect to the United States Supreme Court and Justice Stewart, “I knew safety when I saw it,” and more importantly, I saw what was NOT safety. Patient safety may be, in most people’s minds, the concept that if everything is done correctly to (and for) a patient, then the result is “good” and that the patient “will do well.” This definition does not work nearly as well in some specialties like anesthesiology, since our patients’ outcomes are not always “good”: sometimes, our patients do not do well intraoperatively or postoperatively, not because of our lack of providing sufficient safety, but because of the patients’ own disease. Safety means much more than a good patient outcome without complications—we have all been involved in caring for patients in various circumstances in which major errors were committed, yet the patients withstood the insults without negative sequela. Does this mean that the care we provided was “safe”?

The Patient Safety Leadership Fellowship did for my professional career, and me in one year, what I had not been able to crystallize in my own mind for decades—understand that safety is a journey. It is a process through which even small changes can improve everything in the patient’s course of care, not just the ultimate outcome. Being able to interact with professionals involved

in the provision of health care—physicians, nurses, administrators, coders, insurance underwriters, computer programmers, etc.—was one of the great educational opportunities of an entire career. There, we learned how developing a safe episode of care can involve, for example, “big data” and pulling thousands of records full of clinical information; analyzing these data such that patterns and associations can be recognized; testing these connected clinical data in other clinical scenarios to establish a stronger relationship; and sharing the data with other clinicians so that external validation can occur. These steps seem obvious and mundane, until one tries to make use of these data and realizes that the data have to be accessed from secure sites; have to be in the correct format; have to pass innumerable HIPAA and security tests; have to be protected and perhaps encrypted for storage and later retrieval; and many other steps intended to keep the data anonymous and safe. Medical school, residency, fellowship, and clinical practice do not prepare us with the special skills required for effective use of these data. The Patient Safety Fellowship did.

Leadership Levels Evolve Perspective on Patient Safety Improvement

by John H. Eichhorn, MD (2004-05)

While anesthesia patient safety as a concept keys off the idea that “no patient shall be harmed by anesthesia care” (the APSF mission), “leadership” in the application of that concept involves multiple issues that can be harder to define. The Patient Safety Leadership Fellowship experience was very important in first cementing in a foundation of background knowledge in the rather highly specialized area of patient safety research and experience. Then, over time, interaction and reciprocal learning with diverse very knowledgeable faculty and extremely diverse classmates facilitated a perspective on leadership in patient safety. This perspective naturally sorts into different levels, all of which are important to the advancement of the “cause” of patient safety.

First (and particularly in the specialty of anesthesiology), leadership involves personal behavior and setting a personal example of delivering maximally safe care. Whether teaching residents, working with advanced practice providers, or providing one-on-one anesthesia care, the true patient safety leader will always practice what he or she preaches. With the current climate of “production pressure” in the perioperative environment, one central component is to resist constantly the coercive push to cut corners. Potential examples abound. Suffice it to say that, in my department, I am known as the faculty member who will take

See “Leaders,” Next Page

Fellowship Inspires Patient Safety Leadership

“Leaders,” From Preceding Page

the additional minute or minutes immediately pre-op in Holding to call and get the dialysis patient’s current potassium value, or find the CT image of the airway in the electronic record, all the while discussing the issue out loud so everyone involved knows why. The strength and resolve to be resistant to production pressure (which is, arguably, now the greatest threat to anesthesia patient safety) was significantly bolstered by the leadership fellowship experience and resulting mindset.

Next is translating the example of personal behavior to the challenge of leadership at the “institutional” level. Today, this may involve one hospital or medical center or, increasingly, a “system” of related locations within one practice organization. Beyond cultivating an environment of resistance to dangerous practice omissions or commissions from pressures to cut corners, institutional leadership in patient safety today must address the subject of standardization. Anesthesiology practice is both science and art, combined into a process. The study of process improvement exemplified by Deming, six-sigma, “lean,” the Toyota method, and/or high-reliability organizations, allows application to the challenge of patient safety. In anesthesia especially, but for all fields, striking a viable balance in all members of a professional group between individual clinical habits/preferences and more standardized evidence-based and safe “best practices” is among the major challenges for an institutional patient safety leader. Learning how to do that can be inspired by a course or fellowship, but it usually takes significant trial-and-error experience to actually accomplish.

Finally, patient safety leadership can involve the highest level: influencing and improving national or even international policy and practice.

Organizations such as the APSF, the ASA, the IARS, the AANA, the AAAA, and the WFSA—all with major publications, internet, and social media networks, meetings, advocacy mechanisms, etc.—offer broad and powerful platforms for safety leaders to proffer and promote advances in anesthesia patient safety. Again, examples abound, but the APSF campaign, involving Dr. Cowles, to prevent surgical fires has been a dramatic success in “getting the word out” and changing practice. Impact can be generated by published and publicized research and epidemiology (such as through mining “big data” as suggested by Dr. Brull above) to elucidate the safest best practices and develop ways to get them implemented. There seems sometimes to be an element of luck (“right place, right time, coincidence of favorable conditions, etc.”) in the spread of patient safety advances, but it is always the original enthusiasm, dedication, and persistence of the creative leaders that starts the ball rolling.

As noted, learning how to be a leader in patient safety can be inspired by a course or fellowship, but it usually takes significant trial-and-error experience to actually accomplish. This should never deter those genuinely interested in making anesthesia practice, or anything in health care, safer for patients. Evolving into a patient safety leader can take significant time and effort, but the enormous satisfaction of promoting policy and practice that improve safety—of the patients of one practitioner or for millions of patients across the globe—can never be measured.

Dr. Cowles is a consultant to the APSF for surgical fire prevention and Associate Professor of Anesthesiology and Perioperative Medicine, MD Anderson Cancer Center, Houston; Dr. Van Pelt is a member of the APSF Executive Committee, Chair of the APSF Committee on Education and Training, and the Nurse Anesthesia

Team Leader for the Divisions of Neurosurgery, Vascular & Thoracic at the Massachusetts General Hospital, Department of Anesthesia, Critical Care & Pain Medicine; Dr. Brull has been a member of the APSF Executive Committee and Chair of the APSF Scientific Evaluation Committee and is Professor of Anesthesiology, Mayo Clinic, FL.; Dr. Eichhorn is the founding Editor of the APSF Newsletter and currently Consultant to the APSF Executive Committee and Professor of Anesthesiology at the University of Kentucky College of Medicine.

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Editorial Note:

As of late 2015, the HRET reports that the previously existing AHA/NPSF CPSLF program has been suspended and is not accepting another class of fellows. At this time, the National Patient Safety Foundation is looking at suitable ways to support this fellowship in the future with the intention of adding a new venture to an already rich legacy.

If you would like your name to be added to a contact list for future opportunities and updates, please email Patricia McGaffigan (pmcgaffigan@npsf.org) or visit the NPSF website to see the exciting, innovative work being done.

apsf APSF Website Offers Online Educational DVDs

Visit the APSF website (www.apsf.org) to view the following DVDs and request a complimentary copy.



- Opioid-Induced Ventilatory Impairment (OIVI): Time for a Change in the Monitoring Strategy for Postoperative PCA Patients (7 minutes)



- Perioperative Visual Loss (POVL): Risk Factors and Evolving Management Strategies (10 minutes)



- APSF Presents Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss Ischemic Optic Neuropathy (18 minutes)

Ultrasound-Guided Subclavian Vein Catheterization: Evidence and Practice

Carly C. Barron, MSc; Andre Y. Denault, PhD, ABIM-CCM; and Manoj M. Lalu MD, PhD

Central venous catheterization is a common procedure with more than 5 million central venous catheters (CVC) implanted each year in the United States.^{1,2} Approximately 8% of hospitalized patients require central venous access during the course of their hospital stay.²

Appropriate selection of cannulation site depends on the indication, short vs. long-term requirements, as well as the associated risks. Site of cannulation is also dependent on convenience, ease of access, as well as patient anatomy and comfort. Common sites for insertion include the internal jugular, subclavian/axillary, and femoral veins. While previous research has demonstrated that risks of mechanical complications between jugular and subclavian sites of insertion are approximately equal,²⁻⁷ some suggest that insertion at the subclavian site may be associated with a lower risk of infection and thrombosis compared to the internal jugular site.⁵

Studies have shown that employing ultrasound (US) guidance among those who are experienced in its proper use for central vein catheterization can reduce the rate of failed punctures, complications, as well as performance time.^{5,7-9} Evidence to support US-guidance when inserting through the internal jugular vein includes several meta-analyses and recent clinical practice guidelines; however, a comprehensive review for subclavian vein insertion has not been performed. Thus, our group conducted a systematic review and meta-analysis of randomized controlled trials to determine the safety and efficacy of US-guided subclavian vein catheterization compared to the traditional "blind" landmark method.¹⁰ The following highlights our recently published systematic review and describes the technique of US-guided vein catheterization.

Summary of Our Recent Work

A search of Medline, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and CINAHL (to September 2014) was conducted.¹⁰ We included all randomized control trials comparing US to the landmark technique for subclavian catheterization in adult populations. Since there are variations in the US technology used across specialties, sonographic Doppler or two-dimensional (2D) US imaging, as well as dynamic and static use of US were considered in our study. Outcomes of interest included safety and failure of catheterization.

Ten out of 601 studies met inclusion for review (N=2,168 study participants). We found that overall complication rates were reduced with US compared to the landmark group (odds ratio, 0.53; 95% CI, 0.41-0.69). Other subgroup analyses suggested that dynamic 2D US decreased inadvertent arterial puncture, pneumothorax, and hematoma formation. These adverse events, although uncommon, are clinically significant and potentially life-threatening. Use of routine US may prevent misadventures of the needle that lead to these complications.¹⁰

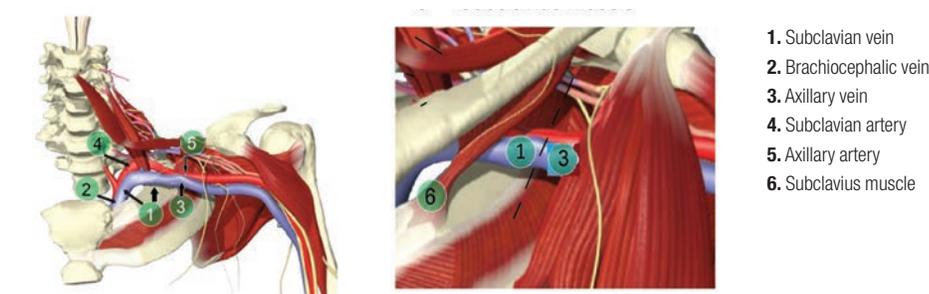


Figure 1. Subclavian and axillary vein/artery anatomy. The subclavian artery (SCA) and subclavian vein (SCV) borders are at the lateral edge of the first rib, and not specifically to the clavicle (although this is easier to remember). The third part of the SCA continues as the axillary artery and the axillary vein becomes the SCV at the lateral border. The third portion of the subclavian artery runs downward and lateral from the lateral margin of the scalenus anterior to the outer border of the first rib, where it becomes the axillary artery. (Gray's Anatomy: The Anatomical Basis of Clinical Practice [40th ed.], Churchill-Livingstone, Elsevier, 2008, ISBN 978-0-443-06684-9.) & (With permission of Denault et al. Basic Transesophageal and Critical Care Ultrasound 1st Edition, CRC Press Taylor & Francis Group 2016; Anatomical images with permission of Primal Pictures, Wolters Kluwer Health.)

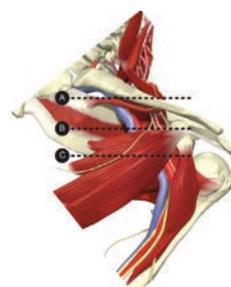


Figure 2. Ultrasound of axillary vasculature. (A–C) Ultrasound examination in a transverse plane of the subclavian vein (SCV), axillary vein (AV) and axillary artery (AA) from (A) under the clavicle, (B) mid-clavicular and (C) distal positions. Air bubbles (arrow) are often seen in patients with an ipsilateral peripheral venous catheter. (With permission of Denault et al. Basic Transesophageal and Critical Care Ultrasound 1st Edition, CRC Press Taylor & Francis Group 2016; Anatomical images with permission of Primal Pictures, Wolters Kluwer Health.)

Our analysis also suggested that the use of dynamic 2D US significantly reduced failed catheterization rates when compared to the landmark technique (risk ratio, 0.24; 95% CI, 0.06-0.92). A review by the Cochrane group (investigating US use for femoral and subclavian line insertion) also suggested benefits of US use; however, this publication did not include more recent studies identified in our study.¹¹ In summary, significant decreases in both failed catheterizations and adverse events are associated with dynamic 2D US-guidance. These results should still be interpreted with caution as the included studies had wide variation with regards to the patient populations, clinical settings, operator experience, as well as details of the US technique. Despite these limitations, significant decreases in both failed catheterizations and adverse events are associated with dynamic 2D US-guidance. Our group's recommendations on how to perform US-guided subclavian vein cannulation are reviewed below.¹⁰

US-Guide Subclavian Vein Catheterization Technique

The subclavian vein and artery are found at the junction of the intrathoracic cavity and the extra-thoracic zone (Figure 1). The subclavian vein extends from the axillary vein as it passes above the first rib and under the subclavius muscle and the clavicle. Depending on the patient's size, adipose tissue and muscle structure, the subclavian vein is situated approximately 1–4 cm deep below the skin and easily identified by US.

In order to image the axillary and subclavian veins, the supine patient is placed in Trendelenburg (5–10°), to promote venous drainage towards the upper thorax and increase the axillary vein diameter, and potentially decrease the risk of entrainment of air. We recommend beginning imaging in short axis, in order to display the vessels transversely, and placing the probe at the distal clavicle where the axillary artery and vein

See "Ultrasound," Next Page

Dynamic Ultrasound May Facilitate Subclavian Cannulation

“Ultrasound,” From Preceding Page

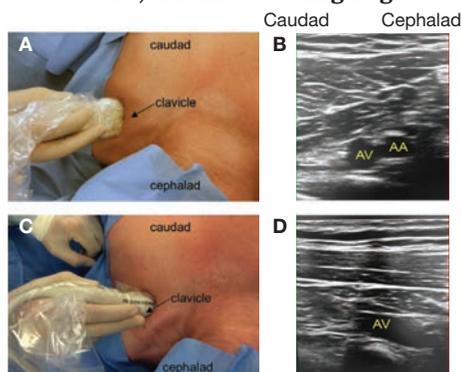


Figure 3. **Axillary vein.** (A, B) Transverse and (C, D) longitudinal position of the ultrasound probe with imaging of the left axillary vein (AV) and the left axillary artery (AA). (With permission of Denault et al. *Basic Transesophageal and Critical Care Ultrasound 1st Edition*, CRC Press Taylor & Francis Group 2016.)



Figure 4. Positioning of operator, probe, and needle.

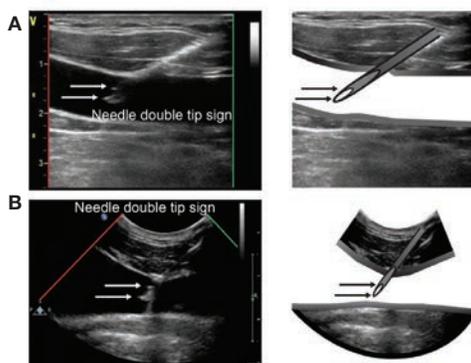


Figure 5. **Double tip sign.** Ultrasound images of the needle in a long axis view with the double tip sign are shown using (A) linear and (B) curvilinear microconvex probes. (With permission of Denault et al. *Basic Transesophageal and Critical Care Ultrasound 1st Edition*, CRC Press Taylor & Francis Group 2016.)

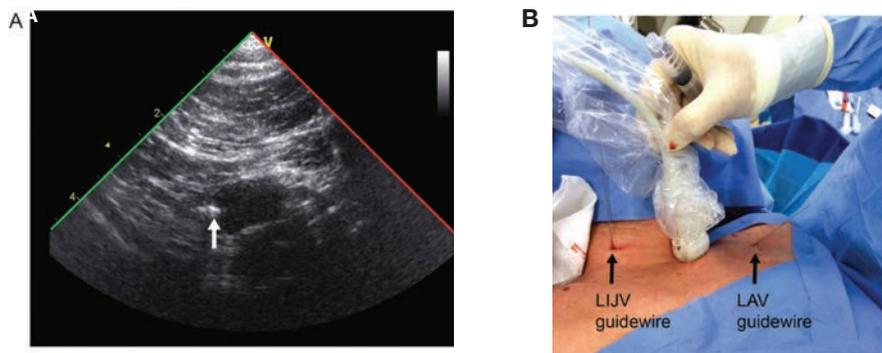


Figure 6. **Axillary vein guidewire.** (A) Guidewire coming from the left axillary vein (LAV) (arrow) (B) In order to see the guidewire the ultrasound probe can be positioned above the LAV or along the left internal jugular vein (LIJV) just above the left clavicle. (With permission of Denault et al. *Basic Transesophageal and Critical Care Ultrasound 1st Edition*, CRC Press Taylor & Francis Group 2016.)

are the largest and most superficial (Figure 2). The axillary artery can be identified by pulsations, while the vein will collapse under the probe's pressure or with deep inspiration. Another way to confirm the location of the axillary vein is to use color or pulsed wave Doppler. This is most effective in the long axis view achieved by rotating the probe 90° (Figure 3).

The ideal spot to puncture the vein is approximately located at a third of the distance between the clavicle and axilla (at this location the vein being cannulated is anatomically speaking the axillary vein, Figure 4). In a patient who is awake, local anesthesia is administered by inclining the needle 45° towards the probe's center with a short axis view. Tilt the probe to the patient's head once the needle has penetrated a few centimeters of subcutaneous tissue to visualize the luminescent tip, or the needle's shaft, which will produce a characteristic “double echo” sign (Figure 5).

After confirming the needle is aligned towards the center of the vein, continue introducing the needle (with continuous aspiration applied to the syringe), until the needle is seen penetrating the vein and blood enters the syringe. At this point, the US probe can be put aside and, with the needle held in place, the guidewire can be advanced into the vessel (Figure 6). Confirm that the guidewire is in the axillary vein prior to dilation and catheter insertion. If the guidewire is not well seen, examine the adjacent internal jugular vein to exclude malposition of the guidewire in the internal jugular vein. Another location for misplacement of the guidewire is in the ipsilateral innominate vein, and can be excluded by moving the US beam downwards to the clavicle to visualize this vessel.

In summary, given the proposed benefits of dynamic US use, we would encourage practitio-

ners to review and adopt this technique when cannulating the subclavian vein.

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Q&A: Reader Questions Fire Risk of Petroleum-Based Products

Q Dear Q&A,

In the hospitals where I have practiced, there have always been eye ointments available, most of which are petroleum-based, for corneal protection along with eye tapes. In our practice, it is common for the surgeons to request the use of this lubricant without tapes or adhesive dressing to the eyes when performing procedures on the head and neck, most often in the presence of endotracheal anesthesia. These surgeries commonly involve electrocautery. I have seen literature recommending all petroleum-based products be restricted from the operating room. I have seen a number of hospital policies that ban use of petroleum products and strong warnings against use in other locations where oxygen is administered by nasal cannula, such as with home COPD users. Does the APSF have any position on the use of petroleum-based eye ointment in head and neck surgeries or on the use of petroleum-based products in the operating room in general? Does the eye ointment commonly used by anesthesia professionals present a fire risk? My understanding is that the ointment, as well as the glycerin-based substitute carry a flammability rating of one. I am assuming that the use of such ointment would be against recommendations in surgeries utilizing an open oxygen source. Is this the case?

The use of lubricant in this manner has never been implicated in an operating room fire here. Does the foundation have any reports implicating the lubricant in such a fire?

Thank you for your time and your strong role in patient advocacy, lending support to the members of our profession against practices that could cause harm.

*Rebekah L. Scotch, MD
NorthStar Anesthesia
Worcester, MA*

A Dear Dr. Scotch:

Thank you for your question and your interest in prevention of surgical fires. Here are some answers to the questions in your letter.

Does the APSF have any position on the use of petroleum-based eye ointment in head and neck surgeries or on the use of petroleum-based products in the operating room in general?

Specific to ointments, the APSF does not have a discrete position on the use of petroleum-based eye ointments. However, the APSF does take a leading role in efforts and education to prevent surgical fires. We focus mainly on reducing the fire risk by limiting the concentration of the open delivery of oxygen to less than 30% FiO₂ or to control the airway with an LMA or endotracheal tube if a higher oxygen concentration may be required.

Some debate exists if lubricant is needed, prevents harm, or even increases risk for ocular trauma. Some believe the best corneal protection is provided by taping the eye in a "lash to lid" fashion where the upper lash is approximated to lower lid and then the eye taped closed.

Does the eye ointment commonly used by anesthesia professionals present a fire risk?

Yes, of the 3 elements needed for a fire (fuel, an oxidizer, and ignition source) the anesthesia providers are usually responsible for controlling the oxidizer (oxygen and nitrous oxide) concentration. Application of petroleum based eye ointment is one of the few instances where anesthesia providers are responsible for the fuel source.

My understanding is that the ointment, as well as the glycerin-based substitute carry a flammability rating of one. I am assuming that the use of such ointment would be against recommendations in surgeries utilizing an open oxygen source, is this the case?

Petroleum/paraffin based ointments are flammable, as are most substances, in an oxygen-enriched environment. Flammability ratings are based upon room air concentration of oxygen and not an increased oxygen concentration. The proximity of the fuel, such as ointments, to open delivery of oxygen in concentrations greater than 30% and to an ignition source such as an electrosurgical unit (ESU) establishes the surgical fire risk. Another factor to consider is the amount of lube applied. A thin coat is more prone to ignite because of inability to dissipate heat over a large amount of ointment.

The use of lubricant in this manner has never been implicated in an operating room fire here. Does the foundation have any reports implicating the lubricant in such a fire?

Since reporting of surgical fires is not mandated uniformly across the US, incidence really cannot be calculated. One surgical fire case describes the open delivery of oxygen via cannula, petroleum-based lube in the eyes, and use of an ESU to remove skin lesions near the eye that resulted in second-degree facial burns. Again, a confluence of all 3 elements needed to create a fire. If the oxygen concentration is kept to less than 30%, especially in cases of an intubated patient, and the ignition source is distant, this greatly reduces the risk for fire. So when in doubt, limit the oxygen concentration!

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See the APSF Fire Safety Video Online at
<http://apsf.org/resources/fire-safety/>

The APSF sometimes receives questions that are not suitable for the Dear SIRS 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.

From APSF Educational Videos to Your Practice: How to Make It Happen

by Robert K. Stoelting, MD, President, APSF

The APSF Board of Directors Workshop on Saturday, October 24, 2015, in conjunction with the annual meeting of the American Society of Anesthesiologists, in San Diego, CA addressed the topic, *From APSF Educational Videos to Your Practice: How to Make it Happen*.

Dr. Jeffrey M. Feldman introduced the APSF operating room fire safety video and noted that obstacles to eliminating preventable fire injuries include (1) reflex use of 100% oxygen by open delivery (face mask, nasal prongs) during monitored anesthesia care and (2) reluctance to control the airway during minor procedures often leading to open delivery of oxygen. Education on sedation with low levels of supplemental oxygen (<30 %) or no supplemental oxygen is needed. Methods for blending oxygen to control the FIO2 may not be readily available, and one may need to consider non-invasive ventilation techniques such as BIPAP.

Dr. Lorri A. Lee introduced the APSF videos dealing with perioperative visual loss (POVL) and the companion video presenting various scenarios for obtaining informed consent for patients at risk for POVL. It is important to recognize that posterior ischemic optic neuropathy (PION) following spine surgery, unlike central retinal artery occlusion, is not caused by pressure on the globe. PION seems to be associated with venous congestion of the head (head down prone position). There is increasing acceptance that the informed consent process should include the risk of POVL in selected patients. However, the value of the informed consent to the patient is dependent on those responsible for the patient's care to be cognizant of the evolving strategies designed to reduce the risk of POVL.

Table 1: Risk Factors Associated with Ischemic Optic Neuropathy After Spinal Fusion Surgery: The Postoperative Visual Loss Study Group (*Anesthesiology* 2012;1016:274-82)

Obesity*
Male gender*
Wilson frame*
Lower % colloid administration*
Longer anesthetic duration
Greater estimated blood loss

*significantly and independently associated with developing ischemic optic neuropathy after spinal fusion surgery

Table 2: APSF Recommendations for Best Practices in Patients at Risk for Perioperative Visual Loss (POVL)

Informed consent should include the remote risk of POVL
If the risk of POVL is not part of the Surgical Informed Consent, it should be part of the Anesthesia Informed consent
The informed consent should include a discussion of risk factors and steps to take to reduce the likelihood of POVL
Controlled hypotension is not recommended

Dr. Feldman's and Dr. Lee's introductory comments set the stage for small group discussions to explore strategies to implement the content of the videos into best practices (Figure 1, Tables 1-2) and to share options to overcome barriers to implementation of the safety practices described in the videos.

APSF believes that educational videos provide advantages compared with the traditional written report when addressing anesthesia patient safety issues and advocating for "best practices" to reduce the likelihood of the adverse events described in the videos (Table 3).

The learning objectives of the workshop were

- Apply the content of the patient safety videos as a vehicle to implement best practices in the operating room.
- Recommend approaches to overcome implementation barriers to safety practices described in the videos.
- Understand strategies for utilizing videos for safety improvement

Prevention and Management of Operating Room Fires

<http://www.apsf.org/resources/fire-safety>

Despite the fact that we know which patients are at risk for fire (surgery above T5 and use of an ignition source in proximity to an oxygen enriched atmosphere) and understand how to prevent a fire (minimize the concentration of oxidizer [oxygen, nitrous oxide]), SURGICAL FIRES CONTINUE TO OCCUR. The root cause of serious fires is typically the use of supplemental oxygen via an open delivery system, thus creating an oxygen-enriched atmosphere in proximity to an ignition source. Anesthesia professionals have direct control over the concentration of oxygen and the method of administration.

Perioperative Visual Loss (POVL)

<http://www.apsf.org/resources/povl/>

Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss (POVL)

<http://www.apsf.org/resources/povl-consent/>

APSF believes that increased awareness and understanding of risk factors associated with postoperative visual loss (POVL) is a timely patient safety topic. Peer-review literature and data from the American Society of Anesthesiologists (ASA POVL Registry) are evolving in a manner that suggest a patient profile at risk for POVL and steps to take in the surgical and anesthetic management that might decrease the incidence of this devastating complication. There seems to be increasing acceptance that the informed consent for surgery and anesthesia should include the risk of POVL in selected patients. Yet the value of the informed consent to the patient is dependent on those responsible for their care to be cognizant of evolving information and strategies designed to reduce the risk of POVL.

Small Group Discussions

Comments and recommendations from the small group breakout sessions following presentation of the videos included

- An operating room fire was a personal experience of several of the attendees or they were aware of an operating room fire in their practice group. POVL was not a common experience among the attendees.
- The APSF recommendations for best practices for patients at risk for an operating room fire were supported by the attendees, but their acceptance sometimes was not instituted until after an adverse event had occurred.

See "APSF Videos," Next Page

Fire Prevention Algorithm Exemplifies Educational Value

“APSF Videos,” From Preceding Page

- There was interest in adding a “time out for fire safety” to the electronic medical records.
- The need for technology (blenders) to titrate the delivered concentration of oxygen was emphasized.
- POVL was an uncommon experience, but the APSF recommendations for best practices in patients at risk for POVL were supported with the caveat that surgeons would likely be reluctant to endorse the need for inclusion of this complication in the informed consent. A personal relationship with the surgeon is important in gaining acceptance of inclusion in the informed consent as part of the at-risk patient’s care. There was agreement that the anesthesia professional should include POVL in the informed consent for at risk patients if the surgeon declined to do so.
- Education (including simulation) for all those caring for patients (especially nurses and surgeons) was viewed as critical for fire safety (understanding that 30% oxygen should be the maximum open delivery concentration) and POVL (recognition of risk factors and the informed consent process).

OR Fire Prevention Algorithm

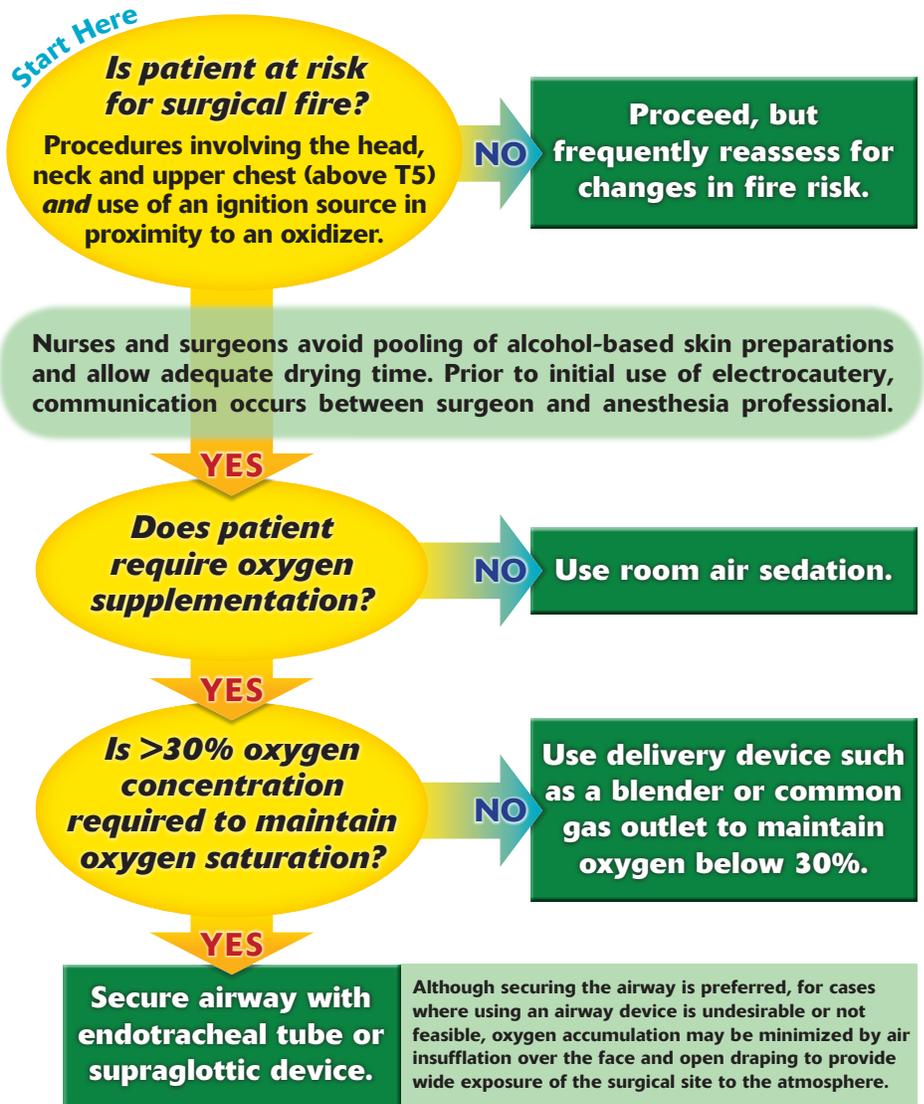


Table 3: Advantages of Educational Videos in Advocating Best Practice Changes

Readily available and free
Viewed at learner’s convenience
Provide a concise and clear message
Can be shared with others
Enduring, but can be updated as needed
Publicly available (accessible to patients)



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

Figure 1: APSF fire prevention algorithm (can be downloaded from APSF website, http://www.apsf.org/resources_safety.php)

A Statement by the Executive Committee of the APSF

From time to time, the Anesthesia Patient Safety Foundation reconfirms its commitment of working with all who devote their energies to making anesthesia as safe as humanly possible. Thus, the Foundation invites collaboration from all who administer anesthesia, all who supply the tools of anesthesia, and all who provide the settings in which anesthesia is practiced, all individuals and all organizations who, through their work, affect the safety of patients receiving anesthesia. All will find us eager to listen to their suggestions and to work with them toward the common goal of safe anesthesia for all patients.

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In This Issue:

New Developments for the Management of Sepsis

Perioperative Fluid Management: Cheers to the Dream of Moderation

Low Tidal Volume Ventilation in the Operating Room (OR)—Where Are We Now?

Use of Capnography during Moderate Sedation by Non-Anesthesia Personnel in Various Clinical Settings

APSF Awards Two Safety Scientist Career Development Awards



Save the Date

Wednesday, September 7, 2016

Royal Palms Resort and Spa, Phoenix, AZ

APSF-Sponsored Conference

Distractions in the Anesthesia Work Environment: Impact on Patient Safety

See details inside