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NEWSLETTER

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Emergency Manuals: The Time Has Come

Michael F. Mulroy, MD, for Emergency Manual Implementation Collaborative

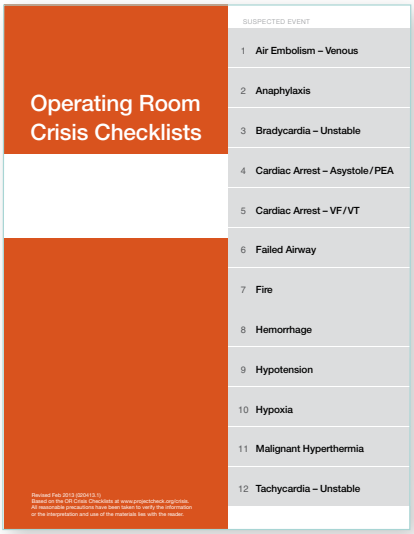

Figure 1. Table of Contents of Ariadne Group checklists.

It was a "standard" interscalene block for shoulder surgery, a single injection of a ropivacaine/tetracaine mixture under ultrasound guidance. But then the convulsion started; the patient lost consciousness and stopped breathing. The blood pressure dropped, but sinus rhythm was maintained. The anesthesiologist reported: "I sort of froze: Four people were doing a lot of things at once, it was chaotic, but I remembered to get the checklist." The checklist he remembered was the ASRA guideline for managing local anesthetic toxicity (LAST) that he had just simulated at a meeting, and which was now posted on the operating room wall. The checklist was read out loud; administration of a large dose of propofol (drawn up and being connected to the IV) was immediately stopped and Intralipid™ given instead in the correct dose. After following the steps on the list, the patient awakened with no permanent complications, and received surgery at a later date.

This is the story shared by Paul Preston, MD, of the Kaiser Hospital system in Northern California. He added that "using the checklist really helped the team get organized and more effectively do the correct steps. It greatly added to situational awareness. Nobody could remember the exact dose of Intralipid even though two of the providers had been through LAST simulation a month earlier—this let the team rapidly get it right."

The reality is that none of us can any longer function as that "lone expert" recalling every procedure and drug dose from memory, especially in crisis situations. The American Heart Association has developed algorithms for managing cardiac arrest, the MHAUS association has a detailed checklist for managing malignant hyperthermia (www.mhaus.org), the Central Line Bundle is now used to prevent infections

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APSF Survey Helps To Establish Pre-Induction Checklist

by Robert K. Stoelting, MD

The Anesthesia Patient Safety Foundation (APSF) Executive Committee believes that a Pre-anesthetic Induction Patient Safety (PIPS) checklist offers an opportunity to pursue the foundation's vision that "no patient shall be harmed by anesthesia."

In this regard, the APSF created a 22-question survey (www.surveymonkey.com/s/3VHDTJY) to determine anesthesia professionals' views on the perceived value of a PIPS checklist and the observations that should be part of the checklist. Those responding to the survey were asked to prioritize items for the checklist, based on what they would want to be part of

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Inside:

ANESTHESIA PATIENT SAFETY FOUNDATION (APSF) 2014 GRANT PROGRAM

Announcing Guidelines for Grant Applications to be selected on Saturday, October 12, 2013 (ASA Annual Meeting) and Scheduled for Funding Starting January 1, 2014

Maximum Award is $150,000 for a study conducted over a maximum of 2 years.

THE ANESTHESIA PATIENT SAFETY FOUNDATION (APSF) GRANT PROGRAM supports research directed toward enhancing anesthesia patient safety. Its major objective is to stimulate studies leading to prevention of mortality and morbidity resulting from anesthesia mishaps.

The APSF Scientific Evaluation Committee will designate one of the funded proposals as the recipient of the **Ellison C. Pierce, Jr., MD, Merit Award** that carries with it an additional unrestricted award of $5,000.

ANTICIPATED **2013-2014** NAMED AWARDS

APSF / American Society of Anesthesiologists (ASA)
President's Endowed Research Award
APSF / Covidien Research Award

APSF / American Society of Anesthesiologists (ASA) Endowed Research Award

Submissions due online no later than Sunday, June 16, 2013 (23:59 EDT).
See www.apsf.org for grant guidelines and other information.

APSF Newsletter *guide for authors*

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All submissions should include author affiliations including institution, city, and state, and a statement regarding disclosure of financial interests, particularly in relation to the content of the article.

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NEWSLETTER
The Official Journal of the Anesthesia Patient Safety Foundation

The **Anesthesia Patient Safety Foundation Newsletter** is the official publication of the nonprofit Anesthesia Patient Safety Foundation and is published quarterly in Wilmington, Delaware. Annual contributor cost: Individual–$100, Corporate–$500. This and any additional contributions to the Foundation are tax deductible.

The opinions expressed in this *Newsletter* are not necessarily those of the Anesthesia Patient Safety Foundation. The APSF neither writes nor promulgates standards, and the opinions expressed herein should not be construed to constitute practice standards or practice parameters. Validity of opinions presented, drug dosages, accuracy, and completeness of content are not guaranteed by the APSF.

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Panel on Monitoring of Neuromuscular Blockade at 2012 New York PGA Meeting, Sponsored by APSF

by Robert C. Morell, MD

On Monday, December 17, 2012, at the New York Society of Anesthesiologists Post Graduate Assembly, Dr. Aaron Kopman, Dr. Lars Eriksson, Dr. Glen Murphy, and Dr. Sorin Brull participated in an APSF sponsored panel titled, "Residual Muscle Relaxant Induced Weakness in the Postoperative Period: Is it a Patient Safety Issue?" Drs. Brull and Robert Stoelting, APSF President, served as co-moderators of this timely panel, which set forth the following goals for audience participants:

1. Enumerate the advantages and disadvantages of utilizing different techniques for monitoring neuromuscular function during surgery
2. Recognize the implications of incomplete reversal of neuromuscular blockade in the postoperative period
3. Incorporate strategies to minimize complications of excessive neuromuscular blockade in the postoperative period.

The panel began with **Aaron F. Kopman, MD**, clinical professor of Anesthesiology (Retired) Cornell University, Weill Cornell Medical College, New York, New York who reviewed the basics of monitoring neuromuscular blockade. Dr. Kopman defined the classic train-of-four (TOF) and shared the history of its use from its origination in 1971 by HH Ali. Dr. Kopman reviewed studies in which volunteers received curare and had vital capacity (VC), negative inspiratory force (NIF), and peak expiratory flow (PEF) measured and correlated with the TOF ratio. Subjects' NIF did not return to >90% of baseline until TOF was greater than 90%.

With TOF of approximately 70%, volunteers reported double vision, were unable to drink from a straw, and could not lift their heads off of the bed for 5 seconds. Even at TOF values of 0.9 there were measurable differences in grip strength.

Dr. Lars I. Eriksson, MD, PhD, FRCA, professor and academic chair, Department of Anesthesiology, Surgical Services and Intensive Care Medicine at the Karolinska Institute and Karolinska University Hospital in Stockholm, Sweden presented the *Clinical Consequences and Outcomes after Incomplete Recovery of Neuromuscular Function*. Dr. Eriksson reviewed the molecular pharmacology of neuromuscular function, blockade and recovery from blockade. Dr. Erikkson discussed the pre- and post-synaptic acetylcholine (ACh) receptors and pointed out how presynaptic ACh receptors (N3- nicotinic) are responsible for mobilization of ACh and maintenance of force over time. A subtype of the ACh receptor is responsible for this, and blockade of that receptor subtype is actually responsible for muscular fade. All neuromuscular blocking (NMB) compounds also cause some presynaptic block, which is responsible for fade. Function of the laryngeal musculature and the diaphragm returns faster than does the function of the adductor pollicis (thumb) muscle. Pharyngeal recovery is very slow as well. Risks of aspiration are increased as TOF ratio decreases, and the elderly are at much greater risk of aspiration than young patients with low TOF ratio, particularly because many elderly patients have impaired pharyngeal function at baseline.

It was also pointed out that neostigmine can produce profound weakness when given in the absence of NMB.

Dr. Glen Murphy, director of cardiac anesthesia and clinical research and clinical professor of anesthesiology, University of Chicago Pritzker School of Medicine located in Chicago, Illinois, presented his perspective on *Neuromuscular Management and Postoperative Complications*. Dr. Murphy shared data regarding the association between residual neuromuscular blockade and postoperative pulmonary complications. Patients who experience residual blockade due to the use of longer acting NMB drugs such as pancuronium had worse outcome than patients with residual blockade after short- or intermediate-acting agents, and could have long-term adverse consequences. Dr. Murphy also provided comparisons of patients who were monitored with standard twitch stimulators (subjective evaluation) as opposed to those monitored with the TOF-Watch monitor (objective evaluation). Patients monitored with the TOF-Watch monitor had a lower incidence of residual neuromuscular blockade and a lower incidence of critical respiratory events such as significant oxygen desaturation, pulmonary aspiration or need for emergent tracheal reintubation.

Finally, **Sorin J. Brull, MD, FCARCSI (Hon)**, professor of Anesthesiology at the Mayo Clinic Jacksonville presented *Back to the Future: Trends, Needs, and Developments in Monitoring for Safe Clinical Care*. Dr. Brull discussed subjective techniques for monitoring NMB including visual, tactile, and clinical assessments. Direct visual and/or tactile assessment of the adductor pollicis response requires the ability to see and/or touch the hand and thumb, which is often not accessible. Clinical assessment of leg or head lift or handgrip has been used in the past. Longer duration (10 seconds or more) of head or leg lift or handgrip is more "accurate" than shorter duration assessments. Quantitative assessment of NMB, with baseline assessments prior to administration of neuromuscular blocking drugs, is superior and more accurate than subjective assessments. New devices are on the horizon, including one being developed by Dr. Brull and for which he provided full disclosure regarding any potential conflict of interest.

All presenters agreed that routine careful monitoring of NMB is important and should be performed in all cases in which patients receive neuromuscular blocking agents. Furthermore, all presenters agreed that a TOF ratio of >0.9 is an appropriate goal, and the minimum degree of recovery consistent with adequate neuromuscular function postoperatively. Lesser TOF ratios indicate residual NMB and the potential for adverse events, both long- and short-term. Objective assessment is considered far superior to qualitative or subjective assessments.

Following the presentations, a survey was distributed amongst audience members. Of the 81 respondents, 80 were anesthesiologists and 1 was an anesthesiologist assistant. Sixty-six (81.5%) had more than 10 years of clinical practice, 7 had less than 5 years, and 7 had 5-10 years of practice. Forty-eight (60%) of respondents were in an academic practice model, while 32 (40%) reported being in private practice.

When asked if residual muscle weakness in the PACU is a rare phenomenon, 10 (13.3%) agreed, while 64 (85.3%) disagreed; 1 respondent felt that data were insufficient to have an opinion.

Of the respondents, 73 (90%) disagreed that a TOF > 0.7 confirmed the absence of significant residual drug-induced muscle weakness in the PACU, while 3 individuals agreed; 5 had no opinion. Similarly, 71 respondents (87.7%) felt that normal respiratory and upper airway function in the PACU may not be present until the TOF ratio is > 0.9, while 9 (11.1%) disagreed, and 1 had no opinion. Regarding this question, 8 individuals (9.9%) stated that their response would have been different before attending this panel presentation.

When asked if objective monitoring (twitch measurement) of the intensity of NMB should be utilized intraoperatively on all patients receiving neuromuscular blocking drugs, 64 (87.7%) responded affirmatively, while 8 (10.9%) disagreed

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The Largest Health Care Associated Fungal Outbreak in the U.S.

by Tricia Meyer, PharmD, Emory Martin, PharmD, Richard Prielipp, MD

The recent and tragic outbreak of fungal infections identified in patients receiving products from the New England Compounding Center (NECC) in Framingham, Massachusetts, has now become the largest reported health care associated fungal outbreak in the U.S.[1] Information from this catastrophic event began emerging when the Tennessee Department of Health was notified on September 18, 2012, of a patient with *Aspergillus fumigatus* meningitis. The patient had received an epidural steroid injection for lower back pain at an ambulatory surgery center 46 days earlier. This 56-year-old index patient initially presented to clinicians with neutrophilic meningitis—most typical of a bacterial infection. After antibiotic therapy failed, an infectious disease specialist investigated and verified the fungal infection.[2-4] Ultimately, this 56-year-old index patient did not survive. Eight other patients, including 7 patients treated at the same center as the index patient, were also identified with *fungal* meningitis. Health authorities soon identified that all 9 patients had received an epidural injection with preservative free methylprednisolone acetate (MPA) 80 mg/ml compounded by the NECC.[4] The Food and Drug Administration (FDA) determined through a microscopic review, that fungal contamination was detected in unopened vials of methylprednsiolone.[5] The contaminated MPA was associated with 3 specific lots. An initial voluntary recall on these 3 lots of MPA occurred but was soon followed by an expanded recall of all products distributed from NECC.[5,6] In addition, on October 31, 2012, the FDA announced a voluntary recall of all unexpired products from Ameridose, LLC, a sterile admixing service and sister company of NECC. Regulators found deficits in testing procedures; however, no impurities were identified in any of their products.[6]

As patient data accumulated, the Center for Disease Control and Prevention (CDC) confirmed the principal fungus detected in afflicted patients has been *Exserohilum rostratum*. Although not a typical human pathogen, *Exserohilum* species are environmental fungi that are commonly found in soil and grass.[7] The first patient (the index case) had a laboratory-verified *Aspergillus fumigatus* infection.[2] Both of these fungi are common in the outdoor environment. The CDC, as of March 2013, has found *Exserohilum rostratum* as the primary fungal infection although 22 other species were identified including the *Aspergillus fumigatus* in sickened patients.[7] Tests at both the CDC and FDA laboratories on the preservative-free MPA vials reported the same fungus, *Exserohilum rostratum*, in unopened vials from 2 of the 3 implicated batches. These results support the association between preservative-free MPA vials and the outbreak.[6,7]

Authorities estimate 17,675 vials of the MPA from these lots were distributed to 76 facilities in 23 states. Of the tainted lots, the earliest dating of the vials was beginning on May 21, 2012. Regulatory officials calculated that 13,534 individuals may have been exposed to contaminated drug from these lots through epidural, spinal, paraspinal, peripheral joint or other therapeutic injections.[1,4] Urban and rural hospitals, ambulatory surgery centers, eye clinics, pain clinics, and plastic surgery centers ordered and administered products from NECC. But other compounded products were also found to have been contaminated during testing by the FDA and CDC. They identified both bacterial (variants of *Bacillus*) and/or fungal contamination (*Aspergillus tubingensis, Aspergillus fumigatus, Cladosporium* and *Penicillium* species) in unopened vials of betamethasone (5 lots), cardioplegia (single lot), and triamcinolone solutions (3 lots)-compounds all prepared by the Framingham Massachusetts pharmacy.[6,7]

The most recent CDC statistics report 51 deaths and 730 cases of the fungal meningitis and other related infections in this recent 20 state outbreak.[8] These infections include not only fungal meningitis but paraspinal and spinal infections as well as peripheral joint space infections. Moreover, recent reports often note localized spinal or paraspinal infections such as abscesses and arachnoiditis. Although there have been reports of infections caused by other products compounded at NECC, the CDC and FDA have no evidence to support this link at this time.[9]

Although this outbreak, due to compounding of medications, may prove to be one of the most serious and lethal in recent history, it is not the first tragedy that has occurred from tainted products distributed by compounding pharmacies. The Institute of Safe Medication Practices (ISMP) has published a list of selected pharmacy compounding mishaps related to sterile products that have occurred since the 1990s (See Table 1) from compounding and hospital pharmacies. The list describes 200 adverse events including vision loss, blindness, infection, and death from 71 different compounded products.[10] Interestingly, the same drug, methylprednisolone, was involved in a 2002 *Exophiala dermatitidis* meningitis outbreak due to a contaminated compounded injectable. The clinician's involved with caring for the patients determined that compounding of preservative free corticosteroids requires meticulous sterility to prevent fungal contamination. If sterility is lacking, the concentrated steroids are a suitable media to support the aggressive growth of pathogenic fungi. The author also found that development of the disease may be delayed for up to 6 months post-exposure.[11]

The Compounding Story

Clinicians using compounded medications for the care of patients must recognize that these products are not considered FDA approved or reviewed drugs. These medications are not normally commercially available from a manufacturer in the strength, concentration, or dosage form needed for a specific patient or special application (e.g., epidural injection). Therefore the safety, efficacy, quality, and adherence to federal manufacturing standards may have not been established.[5]

"Compounding" implies a wide range of complexity from the very simple process of adding one medication to an intravenous solution—a process done daily in hospital pharmacies and operating rooms across the country. However compounding could also be the more complex process of compounding multiple ingredients from raw material. Prior to the 1960s, pharmacists in the local corner pharmacies compounded 80% of all dispensed medications. In the early 1960s, pharmaceutical companies began increasing manufacturing of medications. Thereafter, compounding by local pharmacists greatly diminished. This changed when the need for compounded pharmaceuticals reappeared in the 1980s due to, in part, discontinuation of over 8,000 prescription and non-prescription products.[12] The International Academy of Compounding Pharmacists (IACP) estimates that there are 7,500 pharmacies in the United States that specialize in advanced compounding services of which approximately 3,000 provide sterile compounding.[13,14]

Compounded medications are prepared from component ingredients that can be formulated into capsules, syrups, suspensions, external creams, and gels, and injectables including infusions. Compounding pharmacies prepare medications for patients with allergies to preservatives, dyes, or binder, and for individualized dosage strengths for various patient populations (e.g., infants).[13-15] Although all pharmacies may compound, a main function of the hospital pharmacy is to prepare injectables by following strict standards for sterility. These preparations may include total parenteral nutrition, surgical irrigations, chemotherapy drugs, and various medication drips or infusions. Infection risks are much greater from injectable drugs, and standards to prevent these risks have been established by the United States Pharmacopeia (USP). The development of Chapter <797> describes standards and requirements for compounding sterile products in a safe manner (Table 2). USP <797> is a national standard for the process, testing, and verification of any medication prepared for administration to patients.[15]

If a hospital, clinic, or medical facility does not have the resources to prepare the compounded

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Drug Shortages Drive Demand for Compounding Pharmacies - Numerous Infections Reported

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product they may select to purchase the needed product from an outside compounding pharmacy. Although the definition of a compounding pharmacy is a company that prepares medications for a specific patient pursuant to a prescription, many facilities will use *anticipatory* compounding. Anticipatory compounding is making limited quantities of these compounded medications that are not patient-specific but are made for expected patients that will be used in the near future.[15] Recent and recurring drug shortages have also dramatically increased the use of outside compounders when the commercial agent is not available.

Compounding pharmacies are overseen by their individual State Boards of Pharmacy for adherence to Board regulations. The Board oversees the licensure and oversight of pharmacists and pharmacy technicians, the process of filling prescriptions, records, documents, environment,

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Table 1. Selected Pharmacy Sterile Compounding Misadventures (adapted from ISMP Newsletter)[10]

Year	State	Description
1990	Nebraska	4 patients died of a bacterial infection from non-sterile cardioplegia solution compounded in a hospital.
1990	Pennsylvania	2 patients lost their vision after becoming infected by *Pseudomonas aeruginosa* found in indomethacin eye drops compounded in a drug store even though commercial non-steroidal drops were available at the time.
1998	California	11 children became septic—10 tested positive for *Enterobacter cloacae* bloodstream infections associated with contaminated prefilled saline syringes.
2001	California	11 patients contracted *Serratia marcescens* infections following the injection of betamethasone compounded at a community pharmacy.
2001	Missouri	4 children contracted *Enterobacter cloacae* infections from IV ranitidine compounded in a hospital pharmacy.
2002	North Carolina, South Carolina	5 patients developed *Exophiala* infections from contaminated injectable methyl**PREDNIS**olone prepared by a compounding pharmacy; one patient died.
2002	Michigan	Pharmacy preparing injectable methyl**PREDNIS**olone and baclofen recalled the products because of contamination with *Penicillium* mold, *Methylobacterium*, and/or *Mycobacterium chelonae*.
2003	Missouri	Bacteria contamination with *Burkholderia cepacia* found in at least 2 batches of a compounded inhalant solution used by 19,000 patients with chronic lung diseases.
2004	Texas, New York, Michigan, Missouri	36 patients developed *Pseudomonas* bloodstream infections after receiving heparin/saline flushes from multiple lots of preloaded syringes.
2005	New Jersey, California	Up to 25 patients contracted *Serratia marcescens* infections due to contaminated magnesium sulfate mini-bags prepared by a compounding pharmacy.
2005	Minnesota	2 patients were blinded after receiving a compounded trypan blue ophthalmic injection contaminated with *Pseudomonas aeruginosa* and *Burkholderia cepacia.*
2005	California	Sterile talc vials with unwashed stoppers were not sterility tested before distribution from a compounding pharmacy.
2005	Maryland	10 patients died after exposure to cardioplegia solution from 2 lots contaminated with gram-negative rods.
2006	Nevada	1 baby died from a 1,000-fold zinc overdose (mcg and mg zinc sulfate confused) compounded in a hospital pharmacy.
2006	Ohio	1 child died after a compounding error led to administration of chemotherapy in 23.4% sodium chloride injection instead of 0.9% sodium chloride.
2007	Washington, Oregon	2, possibly 3, patients died after receiving an IV colchicine product compounded at a concentration higher than standard (4 mg/mL vs. 0.5 mg/mL) in a compounding pharmacy.
2009	Florida	21 horses died after receiving a compounded vitamin supplement containing vitamin B, potassium, magnesium, and selenium (product not approved in the US).
2010	Illinois	1 child died after receiving more than 60 times the amount of sodium chloride prescribed due to a compounding error in a hospital pharmacy.
2011	California, Florida, Tennessee	16 patients being treated for wet macular degeneration developed severe eye infections due to contamination of **AVASTIN** (bevacizumab) during compounding; one patient lost vision, another patient developed a brain infection.
2011	Alabama	9 patients among 19 died when parenteral nutrition solutions were contaminated with *Serratia marcescens* during compounding using non-sterile components to prepare amino acids in a compounding pharmacy.
2012	California	9 patients developed fungal endophthalmitis after use of the compounded product Brilliant Blue-G (BBG) or receiving injections of triamcinolone-containing products dispensed from the same compounding pharmacy.
2012	Nationwide	More than 200 patients contracted fungal meningitis after receiving methyl**PREDNIS**olone acetate injection prepared by a compounding pharmacy that was contaminated with *Exserohilum* (a brown-black mold) and *Aspergillus* species.

ISMP thanks Eric S. Kastango, MBA, RPh, FASHP, CEO of ClinicalIQ, for his contribution to this table and for serving as an expert for the related article (www.clinicaliq.com).

FDA and State Boards of Pharmacy Provide Oversight of Compounding Pharmacies

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and compliance with the state's laws and regulations designed to protect the public. The FDA authority is for the integrity of the drugs and "Active Pharmaceutical Ingredients" (APIs) that the pharmacy orders, stores, and uses (all raw material should be from FDA registered pharmaceutical ingredient suppliers). The FDA does not regulate pharmacy practice but can step in if the pharmacy is considered to be mass producing rather than compounding. The FDA may inspect any pharmacy at any time to validate that the medications are stored, inventoried, dispensed, or sold by that pharmacy are safe. However, the FDA does not designate a pharmacy as FDA approved. If controlled substances are involved in the compounded product, then the Drug Enforcement Administration (DEA) would also have oversight. Additionally, following of the United States Pharmacopeia USP <797> standards for the compounding of sterile medications is expected and is typically inspected by the state boards of pharmacy. The Pharmacy Compounding Accreditation Board (PCAB) sets national standards to accredit compounding pharmacies. Participation with PCAB is voluntary. Including New England Compounding Center, 98% of compounding pharmacies are not currently PCAB accredited.[12-15]

The NECC was licensed by the Commonwealth of Massachusetts as a pharmacy. Reports indicate that the NECC may have extended beyond its scope of authority as a pharmacy and may have been involved in the manufacture and distribution of prescription drugs without registering with the FDA or the Massachusetts State Board of Pharmacy as a manufacturer and distributor. The FDA is responsible for and oversees manufacturers.[3,14]

When the NECC was identified as the compounding pharmacy responsible for the contamination, authorities found the pharmacy's records showing their clean room had tested positive for bacteria and mold over the past year. The NECC did not take corrective action. The investigators also found failure to use sterilization equipment for the necessary time to assure the drugs were safe. Two of the three steroid tainted lots were shipped before results of sterility testing were confirmed. The NECC may not have followed generally accepted manufacturing processes.[3]

Each time contaminated compounded products harm patients, consumers, clinicians, and society assumes a valuable lesson was learned, and corrections were implemented to prevent this from occurring again. Unfortunately, we are relearning this lesson. As of March of 2013, two separate compounding pharmacies have posted recalls for potentially contaminated products.[16]

Table 2. USP 797 Compounding Conditions: Risk of Contamination for Compounded Sterile Products (CSP)*

**for illustration purposes, not a complete listing of USP Standards*

Low-Risk Level

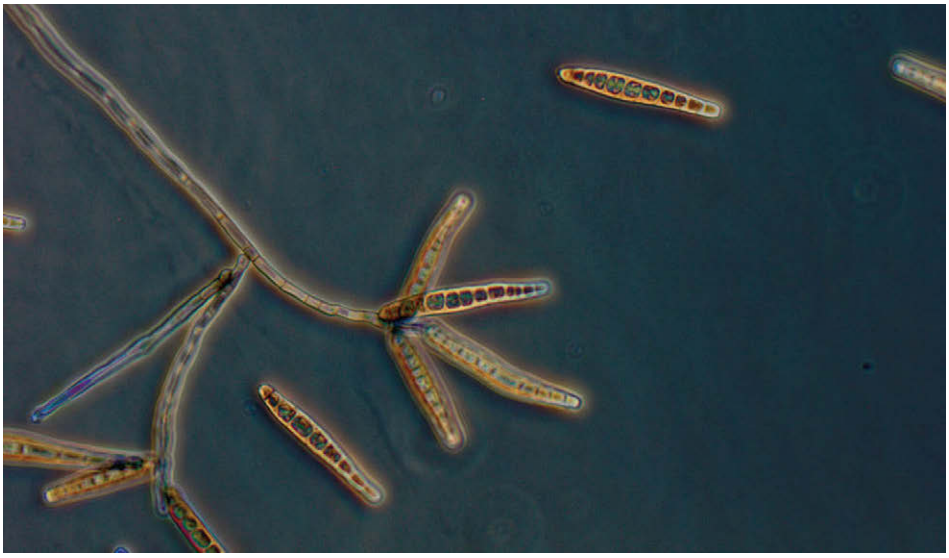
- Compounded entirely in air quality of ISO Class 5 standard (room air with <100 particulates (0.5 µm) per ft^3).
- Involves transferring, measuring, and mixing manipulations with closed or sealed packaging systems.
- Limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles, and transfer of sterile liquids in sterile administration devices.
- In the absence of sterility testing, storage periods of CSP can NOT exceed 48 hrs at room temperature, or more than 14 days at cold temperature, or 45 days if stored in a solid, frozen state (–20 degrees or colder).

Medium-Risk Level

- All conditions under low-risk apply (see above)
- Multiple individual or small doses of sterile products are pooled to prepare a CSP administered to 1 patient multiple times or multiple patients.
- Involves complex aseptic manipulations beyond simple volume transfer.
- Compounding procedure requires long duration.
- The sterile CSP does not contain any broad-spectrum bacteriostatic agents, and are administered over several days. Specific storage conditions apply.

High-Risk Level

- Non-sterile ingredients and components are incorporated, or use of a non-sterile device is used before final sterilization.
- Sterile components or mixtures are exposed to air quality inferior to ISO Class 5 standard (room air with >100 particulates per ft^3).
- Non-sterile ingredients are exposed for up to 6 hrs prior to terminal sterilization
- Non-sterile ingredients are terminally sterilized but not tested for bacterial endotoxins.
- Assumption that chemical purity and content strength of ingredients meet compounding specifications in packages of bulk ingredients.
- The sterile CSP does not contain any broad-spectrum bacteriostatic agents, and are administered over several days in the absence of passing a sterility test.



Exserohilum Rostratum
Photo used with permission of the CDC.

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Largest Fungal Outbreak in US

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Letter to the Editor:

What is the Optimal CVP to Minimize Risk in Patients Undergoing Laparoscopic Hepatectomy?

To the Editor:

As surgical specialties advance, subspecialties within the field are uniting to combine modalities that ultimately benefit patient care. This is evident with hepatic surgeons assimilating laparoscopy for major hepatic resections. The advent of this new technique mandates that anesthesia professionals stay in touch with the changing physiologic environment that the operative field creates and demands. In open hepatic resections, the goals of minimizing hemorrhagic risk and venous air embolism are mitigated by maintaining a central venous pressure (CVP) from 0-5mmHg with the transducer leveled to the site of resection (Giordano C, Gravenstein N, Rice M—unpublished data). This effectively keeps sinusoidal venous pressure low enough to prevent excessive blood loss yet sufficient to minimize the risk of air entrainment. This physiologic milieu becomes unbalanced with the implementation of pneumoperitoneum pressure (PP) to facilitate laparoscopic surgery.

The conundrum begins by appreciating the pressure differential between the CVP and PP impacting the hemorrhagic tamponade effect[1,2] and CO_2 embolic risk.[3-5] Complicating the physiology of these two risks are the compliance, compressibility, and collapsibility of the vessels being dissected. Puncturing a hole in the inferior vena cava as opposed to transecting hepatic sinusoids may result in differences in their volume and rate of CO_2 ingress during PP. The surgical field creates more uncertainty when varying venous structures are periodically stented open by PP distension and mechanical retraction.

The anesthetic balancing act continues with a new variable resulting from the insufflation pressure: abdominal compartment syndrome. Anesthesia professionals must recognize the PP decreases preload and impacts cardiac output, and diminishes renal, hepatic, and splanchnic perfusion pressures. An additional concern is the reverse—the Trendelenburg positioning required to optimally expose the liver. Patient positioning results in significant venous pooling that decreases the intrathoracic CVP and preload, while augmenting the PP-CVP differential. This may abrogate blood loss, but it magnifies the pressure gradient from the operative field to the central venous circulation promoting CO_2 embolization. Currently, no adopted stance on optimal CVP has been voiced, acknowledging the new variables within laparoscopic hepatectomy: PP (intraabdominal pressure [IAP]) and patient positioning.

If the significance of CO_2 embolism is minimal, absent insertion of the insufflation needle into a vessel, then the opposing concerns are the maximum allowable insufflation pressure to view the field and balance hemostatic effects versus the appropriate organ perfusion pressures. Trials of insufflation limits have demonstrated that IAPs greater than 16 mmHg are ultimately detrimental to organ perfusion,[6-8] and therefore should be maintained no higher then 12-14 mmHg. If this is our founding block, despite the notion that some procedures may be done with less PP to adequately view the surgical field, we must now decide on the optimal target CVP strategy and perhaps also intraoperative monitoring for the increasingly common laparoscopic hepatic resection operation. We pose two questions. First, should the target CVP during laparoscopic hepatic resections be different than for open cases and secondly, should transesophageal echocardiography or precordial Doppler monitoring be recommended during these operations?

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Checklists Improve Performance in Emergencies

"Manuals," From Page 1

in the ICU, and ASRA has shared the LAST checklist.[1] We are now adapting to the checklist concept that has been used in aviation for 80 years, and for anesthesia machine checks for 50. We have seen that effective use of the WHO surgical checklist in the operating room reduces morbidity and mortality. The Stanford Patient Simulation Center has an extensive history of developing and testing cognitive aids for operating room teams through simulation.[2] This concept has also been explored by researchers at Ariadne Labs, a joint center for health system innovation at Brigham and Women's Hospital and Harvard School of Public Health, to introduce a broad set of 12 Crisis Management checklists for the operating room (Figure 2).[3]

Simulation testing of such cognitive aids in Palo Alto , Boston,[3] and Seattle[1] has shown, not surprisingly, that performance in emergency situations is greatly improved with a checklist. The use of these tools in teaching new residents how to manage emergency situations has also been demonstrated at Northwestern University.[5] Distribution of emergency manuals in the VA Hospital system has resulted in anecdotal reports of efficacy in real time crisis situations.[6]

While every hospital needs an Emergency Manual that meets their specific needs (including the phone number for fire reporting, the location of the MH kit, etc.), there are several sets of cognitive aids available as potential templates. The Stanford published handbook of checklists[7] is now supplemented by a website with a set of 23 anesthesia cognitive aids (http://emergencymanual.stanford.edu) (Figure 3) and a second website with additional

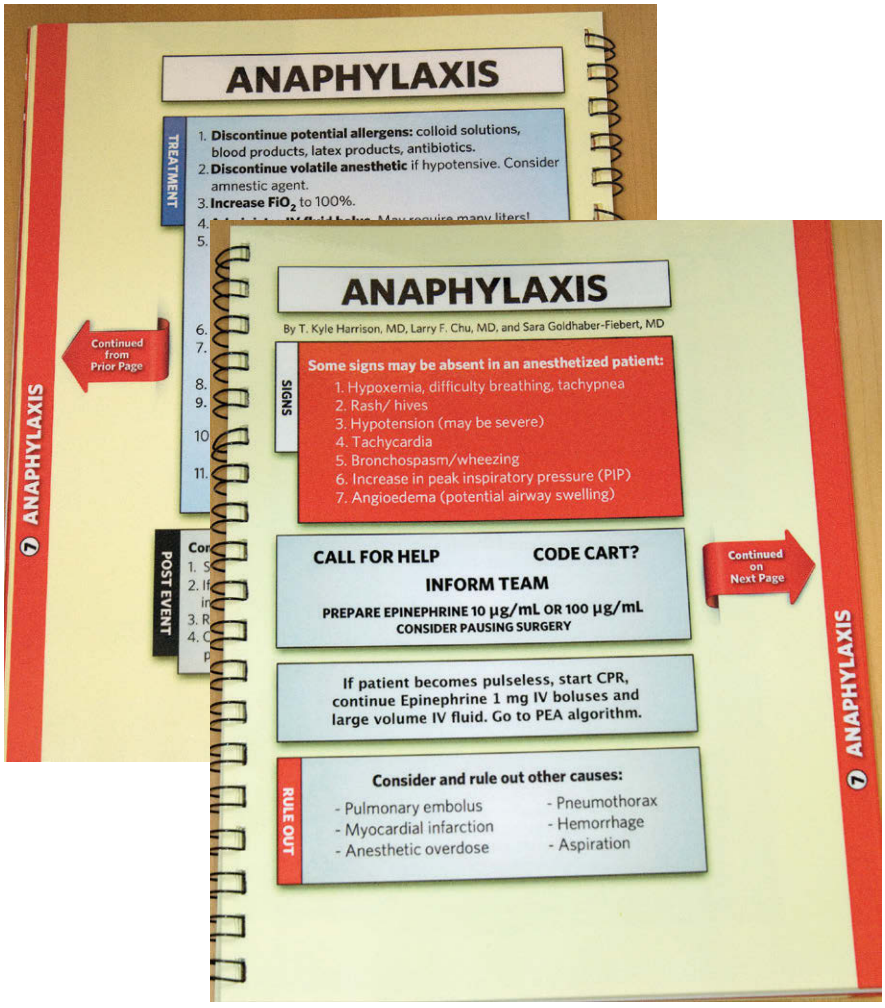

Figure 3. Example of checklist from Stanford Anesthesia Cognitive Aid Group.

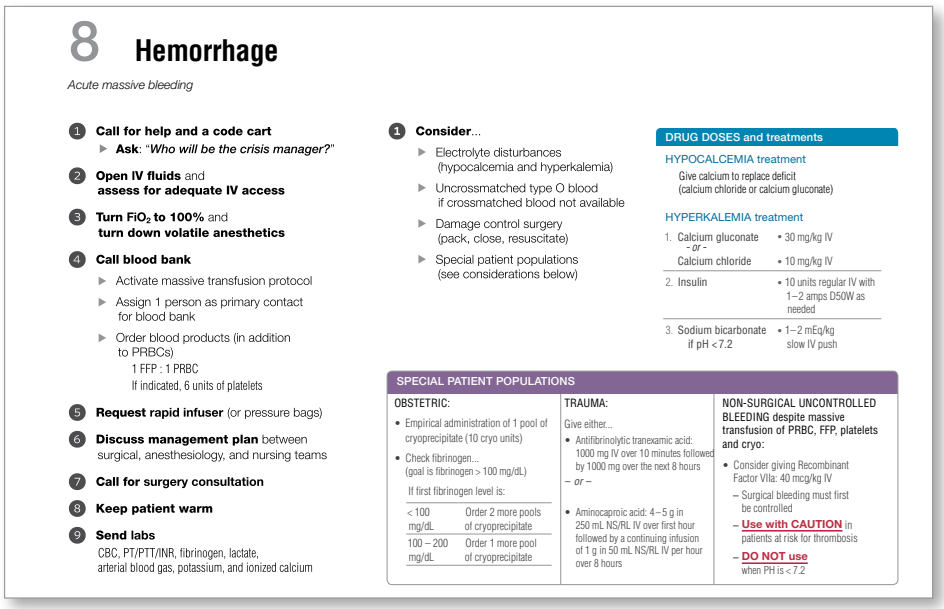

Figure 2. Example of checklist from Ariadne Labs

protocols (www.cognitive aids.org). Another manual of Crisis Checklists for the Anaesthetist[8] is available, but uses more British standards for cardiac emergencies—a North American version may be coming in the future. The LAST guidelines are available from www.asra.com. The 12 checklists developed and tested by researchers at Ariadne Labs are also available at www.projectcheck.org/crisis, which includes a 4-page discussion describing practical ways to adapt and distribute these in operating rooms and a discussion of modifications that may be needed.

But it is not just a matter of buying some books or distributing a set of three ring binders. Experience with the WHO surgical checklist shows just tacking a checklist on the wall doesn't create effective use or team behaviors. Lists must be modified for local use; even the ACLS guidelines aren't

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Cognitive Aids Critical for Crisis Management

"Manuals," From Preceding Page

always suited to the operating room.[9] Institutional support and education is needed, as well as inclusion of all of the staff who might be affected, including surgeons, nurses, and anesthesia technicians. A local "champion" is the best way to ensure broad implementation. There are at least 4 stages:

- acquiring the tools
- familiarization by the staff
- actual use (simulation as the best start)
- eventual cultural change.

This latter concept highlights the need for all members of the team to move away from the traditional reliance on memory and towards the acceptance of cognitive aids, as well as a shift from the cultural expectation of individual perfection, concepts that will likely require several years in a medical system that currently teaches and grades individual responsibility and independent action. Several simulations have shown reluctance of current trainees to use cognitive aids, even when made available.[1]

Crisis checklists will not be used if the potential users are unaware of them and untrained. Neily and colleagues at the VA found that, despite the positive response to the concept by 98 % of staff, 13% and 41% in 2 surveys admitted they were not even aware of the tools.[5] Awareness alone is also not enough—practice is critical. Burden and colleagues found in their simulation trials that a designated "reader" was essential for the more complex scenarios, such as malignant hyperthermia.[10] The ASRA group discovered in their initial simulation that the first guideline was ambiguous and had to be revised to be effective.[1] Using the crisis checklists as templates for multidisciplinary simulation is the ideal way to ensure that the steps are clear, and that all members of the operating team are really prepared to handle emergencies—the Stanford group has been constantly revising their lists based on simulation experience.

Many of these ideas were broached at a collaborative discussion on crisis checklist implementation at the ASA meeting in Washington, DC, in October 2012, and will be refined at a follow-up session in San Francisco. The discussions in DC led to development of an Emergency Manual Implementation Collaborative (EMIC) this spring, which is dedicated to fostering the implementation of crisis checklists in the operating room. The group has established a website for exchange of ideas (www.emergencymanuals.org). If you have a set of Emergency Checklists or Cognitive Aids, or whatever you call them, please share your experiences on this site. Your participation is welcome, especially if you have familiarities with implementation that can ease the path for others, or give good reasons to make it happen.

Although everyone accepts the concept, effective implementation of emergency manuals will not happen automatically, partly because of the rare frequency of such events, but also because of our cultural heritage of independence. It took the airlines many years to arrive at their current state of high reliability, achieved by their emphasis on frequent simulation, adaptation of team training, and heavy use of checklists. We have equal challenges, but hopefully can use their experience to help us make the transition rapidly.

Members of the Emergency Manual Implementation Collaborative include

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APSF Pre-anesthetic Induction Patient Safety (PIPS) Checklist: Results of Survey and Next Step

"Checklists," From Page 1

a safety checklist before induction of their anesthetic (the passenger rather than the pilot).

The intent is to ultimately create a template for a PIPS checklist that could be utilized by anesthesia professionals and anesthesia groups as the basis to create a pre-anesthetic induction patient safety checklist that best fits their practices. Such a checklist is not intended to reflect the steps involved in a pre-anesthetic evaluation and formulation of an anesthetic management plan. The proposed checklist would confirm the status of those characteristics most important for proceeding with anesthetic induction (on the runway and cleared for take-off). Success of this APSF safety initiative may well be "stimulating interest and creating the traction for the national professional societies to act."

An invitation to take the survey was sent 2,229 anesthesia professionals representing members of the American Society of Anesthesiologists, American Association of Nurse Anesthetists, and the American Academy of Anesthesiologist Assistants. Recipients were encouraged to share the survey link with colleagues who wished to express their opinions. Respondents were asked to comment on their perception of the need/value of an APSF PIPS checklist and to rank (high priority, low priority, do not include) the proposed components of the checklist. The survey was opened 738 times and completed 713 times (96.6%) with between 705 and 723 respondents answering each question.

Respondents' years in clinical practice and characteristics of their clinical practice model are summarized in Tables 1-2. More than 80% of the respondents had been in practice more than 10 years, 46.1% characterized their clinical practice model as academic, and nearly 30% practiced in a group of 10 or more members.

Respondents were asked initially to indicate which statement(s) best reflect(s) your opinion(s) regarding the APSF's proposal to develop the content for a template that could be utilized to develop a "PIPS Checklist" (Table 3). Clearly the majority of respondents supported the development of a checklist while many endorsed the statement that the "proposed template content should be utilized only if there is evidence to support its value." Only 2.2% (16 respondents) concluded the "proposed template for development of a checklist is not needed and should not be considered at this time." Comments were

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Table 1: Responses to survey question, "Please indicate your years in clinical practice."

	Percent of responses	Number of responses (n-723)
Less than 5 years	9%	65
5 to 10 years	10.9%	79
More than 10 years	80.1%	579

Table 2: Responses to survey question, "Please characterize your clinical practice model."

	Percent of responses	Number of responses (n-722)
Group practice (less than 10 members)	5.7%	41
Group practice (10 to 30 members)	10.9%	79
Group practice (more than 30 members)	16.9%	122
Solo practice	2.8%	20
Academic	46.7%	337
Hospital based	13.9%	100
Other	3.2%	23

Table 3: Responses to survey question, "Please indicate which statement(s) best reflect(s) your opinion(s) regarding APSF's proposal to develop the content for a template that anesthesia professionals and anesthesia groups could utilize to develop a "PIPS Checklist" that is tailored to the unique needs and characteristics of their practice (check all that apply)." (723 respondents answered this "check all that apply" question.)

	Percent of responses	Number of responses (check all that apply)
APSF should give development of the template content for a safety checklist high priority as it will likely enhance patient safety.	51.3%	371
Our patients expect an anesthesia professional to verify the items that are included on a safety checklist so why not document our actions?	36.9%	267
There is no evidence that utilization of a checklist will likely enhance patient safety, but it is the right thing to do.	9.1%	66
A safety checklist that might be developed from the proposed template would only increase "paperwork" and is unlikely to enhance safety.	5.0%	36
A safety checklist that might be developed from the proposed template content should be utilized only if there is evidence to support its value.	32.8%	237
A safety checklist that might be developed from the proposed template content would be burdensome from a time standpoint in an already busy environment and could detract the anesthesia professional from other important patient safety practices.	6.4%	46
The proposed template for development of a safety checklist is not needed and should not be considered at this time.	2.2%	16

Pre-anesthetic Induction Patient Safety Checklist (PIPS): A Call to Study Efficacy

"Checklists," From Preceding Page

Table 4: Summary of comments that were not supportive of developing an APSF Pre-anesthetic Induction Patient Safety (PIPS) Checklist.

Maybe you should first pilot a study to determine if these checklists indeed improve patient safety.
There is ample evidence in aviation literature and now medical literature that checklists DO NOT solve all problems attendant to a "pretake off mode." Often times the well-intended nature of checklists is defeated by time pressures and frequent interruptions necessitating (under ideal conditions) that the checklist be restarted at the beginning.
There is no reason to increase the complexity and cost of anesthetics unless pilot studies show the potential for enhancing safety.
We may be reaching a point of over-documentation, which elevates the risk of lawyers looking for problems that may not exist, without any real advancement in patient safety.
Little evidence that time outs and checklists have importantly impacted errors in medicine. The solution is not more of the same, but studies to determine other effective means to affect errors.
Duplication of issues already covered in existing checklists (WHO, machine checklist, SCIP protocols) and institutional/universal time out, "huddle."
Redundant and unnecessary.
Too many checklists already (too many will lead to lower safety).
Time taken to specifically document is likely to be non-fruitful, as it will be easy to just check all boxes (electronic check boxes make this very easy).
We are converting medical care into checklist care.
Most of the issues included should have been done before entering the operating room.
The list would create mindless autobots. This is something you learned, should be second nature, and I'm tired of hearing about the airplane pilot blah blah blah.
If individualized, I think the correct checklists can improve awareness but I don't want somebody else's that may not be applicable to our setting.
I do agree that it adds more paperwork, and most people would breeze through the checkmarks anyway. Making providers check off a box may or may not make them more likely to actually DO those things.
Forms/checklists do not substitute for diligence and attention to detail.
These are part of what should-be-routine pre-induction review of our technical readiness. If this proceeds, it should be named more correctly—take out the word Patient from the title.
I am insulted that you think anesthesiologists would need a template to provide good care. Most of these things are basic, like airway assessment (isn't that what we do???).
Many items you covered are part of pre anesthetic evaluation....are you just changing the name of the the evaluation....I see no need to do the pre anesthesia evaluation and then repeat it with a check list.
We need to be careful not to require too many lists, checklists, etc.
Anyone can check boxes and still not have good practice skills. Time spent "checking"cannot take away from clinical care time.

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Prioritization Needed for PIPS Items

"Checklists" From Preceding Page

invited for each question and a summary of comments that urged caution and/or were not supportive for the development of a checklist are listed on Table 4.

The results of prioritizing items to place in the template are shown on Table 5. Based on these results: The APSF is proposing a template of those items that achieved the highest priority plus a "special considerations" box based on comments from several of the respondents (Table 6).

Editor's Note: The next step is APSF's request for proposals (RFP) to study the implementation and performance of the proposed APSF PIPS checklist (see box announcement on page 4, contact Stoelting@apsf.org for RFP guidelines and application).

Robert K. Stoelting, MD

President, APSF

Table 5: Responses to Survey Questions to Prioritize the Content of a Template for Inclusion on a Pre-anesthetic Induction Patient Safety (PIPS) Checklist.

Template Statement	High Priority	Low Priority	Do Not Include
1. Verify suction is working.	94.4%	2.9%	2.7%
2. Verify anesthesia workstation can provide ventilation with 100% oxygen under positive pressure.	90.8%	4.1%	5.2%
3. Verify upper airway status evaluation and availablity of backup airway devices.	85.8%	7.3%	6.9%
4. Verify review of known drug allergies and consideration of possible drug interactions.	83.9%	10.1%	6.1%
5. Verify NPO status and aspiration risk.	82.2%	9.1%	8.7%
6. Verify monitors are functioning, wave forms are present if appropriate and the audible and visual alarms are set.	79.3%	13.3%	7.4%
7. Verify appropriate medications are available including resuscitation drugs.	78.5%	13.0%	8.4%
8. Verify intravenous access is appropriate and functioning.	73.2%	16.5%	10.3%
9. Time out according to existing institutional protocol.	72.2%	13.2%	14.6%
10. Verify blood available if needed.	70.6%	20.1%	9.3%
11. Verify antibiotics administered if appropriate	68.4%	21.4%	10.2%
12. Verify baseline vital signs (including BP and HR) and desirable range for these values during anesthesia.	62.9%	24.5%	12.5%
13. Verify review of medications, laboratory values and radiographic studies relevant to anesthesia.	59.1%	25.8%	15.2%
14. Verify level of surgical fire risk.	52.2%	29.2%	18.6%
15. Verify appropriate steps taken or planned for protection from peripheral nerve injury.	46.0%	36.8%	17.2%
16. Verify noninvasive blood pressure monitor is in the automatic mode.	41.5%	38.3%	20.3%
17. Verify function of operating room table including head down function.	30.0%	47.2%	22.7%

Table 6: APSF Pre-Anesthetic Induction Patient Safety (PIPS) Checklist

- ☐ Suction is working.
- ☐ Anesthesia workstation can provide ventilation with 100% oxygen under positive pressure.
- ☐ Upper airway status has been evaluated.
- ☐ Backup airway devices are immediately available.
- ☐ Patient's significant drug allergies and possible drug interactions noted.
- ☐ NPO status and aspiration risk confirmed.
- ☐ Monitors are functioning with appropriate waveforms.
- ☐ Audible and visual alarms are set appropriately.
- ☐ Appropriate medications including resuscitation drugs are available.
- ☐ Intravenous access (if indicated) is appropriate and functioning.
- ☐ Special considerations for this patient confirmed (may include but not limited to):
  - ☐ Increased risk for operating room fire.
  - ☐ Surgical positioning requirements.
  - ☐ Goals for blood pressure and/or heart rate management.
  - ☐ _____
  - ☐ _____
  - ☐ _____

Survey Asks if Objective Monitoring for NMB Should Be Standard Practice

"Neuromuscular Blockade," From Page 3

and 1 had no opinion. When asked if their response to this question would have been different before attending the panel, 4 (5.5%) said yes.

The eighth question on the survey asked if subjective monitoring (visual or tactile) and clinical tests (head-lift or handgrip) for the presence of residual weakness in the PACU would negate the need for intraoperative objective monitoring. Three (4.2%) of the respondents agreed, while 66 (91.7%) disagreed, and 3 had no opinion due to either insufficient data (2) or the question being outside their area of expertise (1). When asked if their response would have been different before the panel, only 2 respondents said yes.

When the participants were asked if the APSF should encourage the American Society of Anesthesiologists to consider adding neuromuscular function to the ASA Standards for Basic Anesthetic Monitoring (recognizing that standards are considered to be evidence-based), 63 (86.3%) agreed, while 6 (8.2%) disagreed, 1 (1.4%) had no opinion due to insufficient data to have an opinion, and 3 (4.1%) had no opinion due to the question being outside their area of expertise. When asked if their response to this question would have been different before attending this panel, 2 stated yes (2.7%).

Finally, participants were asked if they would support the following addition to the ASA Standards for Basic Anesthetic Monitoring, recognizing that standards are considered to be evidence-based:

Neuromuscular Function
Objective
To aid in the recognition of residual skeletal muscle weakness in the postoperative period owing to the intraoperative administration of neuromuscular blocking (most often nondepolarizing) drugs.

Methods
Qualitative clinical signs such as visual and tactile observations and clinical signs such as head-lift, handgrip, and tidal volume may be helpful, but every patient receiving neuromuscular blocking drugs should have objective monitoring of the intensity of neuromuscular blockade during the intraoperative period and prior to tracheal extubation. Prior to tracheal extubation, pharmacologic antagonism of neuromuscular blockade should be considered based on subjective and objective monitoring to minimize the risk of residual drug-induced postoperative weakness.

Fifty-nine (86.9%) of the respondents agreed, 4 (5.9%) disagreed, 3 (4.4%) had no opinion due to insufficient data to have an opinion, and 2 (2.9%) had no opinion due to this question being outside their area of expertise.

The expert panelists and a majority of the surveyed audience members agree that objective monitoring of neuromuscular blockade should be used routinely in cases where neuromuscular blocking agents are administered. The APSF is very supportive of encouraging the professional associations representing anesthesia professionals to consider this initiative.

Dr. Morell is a private practice anesthesiologist in Niceville, FL and is the co-editor of the APSF Newsletter *and a member of the APSF Board of Directors and Executive Committee and attended this panel presentation at the NY PGA Meeting.*

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Letter to the Editor:

Fire Safety in the Operating Room

To the Editor:

Operating room (OR) fire is considered a sentinel event in today's practice of medicine. Despite the safety guidelines that are currently in place at most hospitals, OR fires still occur anywhere from 50-200 times per year. Recent literature suggests that there is poor communication and preparedness of the OR staff for such events. Furthermore, the lack of accurate air-oxygen delivery systems has been cited as an additional problem.

OR fires traditionally require 3 components, known as the "fire triad": 1) an oxidizer, 2) an ignition source, and 3) fuel.[1] *Oxidizers*, usually supplied by the anesthesia provider, include oxygen and nitrous oxide, and are especially hazardous when an oxidizer-enriched atmosphere exists within a closed or semi-closed system. *Ignition* sources are usually the responsibility of the surgeon, and include electrosurgical or cautery devices, lasers, and heated probes. *Fuel* sources are usually supplied by the nurse or scrub technician, and include sponges, drapes, alcohol-containing solutions, gowns, and a number of other flammable items.[2] The ASA Practice Advisory on OR Fires states that prevention involves 3 components: 1) minimizing an oxidizer-enriched atmosphere near the surgical site, 2) managing ignition sources, and 3) managing fuels.[3]

The anesthesia provider has a pivotal role in OR fire prevention with regard to oxidizer supply. Current oxygen delivery systems allow for delivery of an inspired FiO_2 of 0.24 to 0.90, depending on the oxygen flow rate, via systems such as simple or Venti-masks, non-rebreather face masks, or nasal cannulae.[4] Since 2003 the Joint Commission on Accreditation of Healthcare Organizations (JC) has recommended the use of air or FiO_2 <30% for open delivery systems to prevent surgical fires.[5] The common auxiliary ball-in-tube O_2 flowmeter mounted to most anesthesia machines delivers 100% O_2, which, when used with the above delivery systems, is not ideal, according to the JC recommendations.

An air-oxygen blender (Precision Medical), can easily be mounted on most modern anesthesia machines via a universal mounting bracket and appropriate gas delivery hoses.[6] The blender has a large control dial, which allows users to deliver a precise FiO_2 between 21% and 100%, with a 3% error. Gas blends can safely be delivered to infant, pediatric, and adult patients. After being mounted and connected to oxygen and air lines, this device is also attached to a metering device and an oxygen analyzer. A bleed collar vents the air-oxygen mixture to the atmosphere to maintain FiO_2 accuracy. Air-oxygen blenders offer a simple solution for anesthesia providers to control delivery of accurate oxygen concentrations, particularly at lower FiO_2s. Such a solution allows for better prevention of OR fires and greater compliance with JC recommendations.

The authors have no financial conflicts of interest with Precision Medical or any other air-oxygen blender manufacturer.

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Figure 1. Air-Oxygen blender mounted on the Datex Ohmeda anesthesia machine.

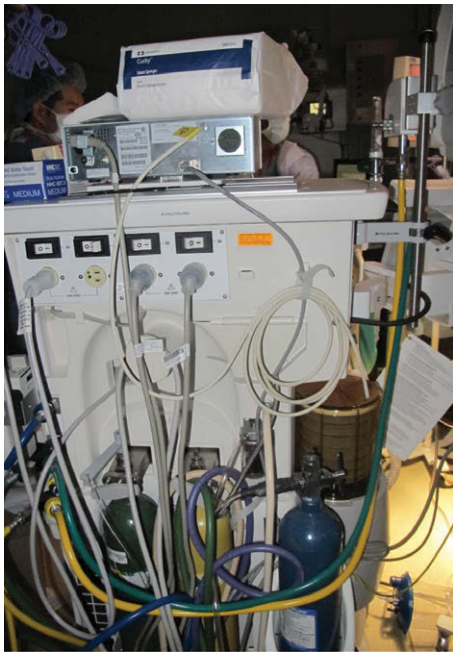

Figure 2. The back of the anesthesia machine, showing oxygen/air connections.

Impact of the Beach Chair Position on Cerebral Perfusion: What Do We Know So Far?

by Torin Shear, MD, and Glenn Murphy, MD

Arthroscopic repair of the shoulder is one of the most commonly performed surgical procedures in the United States. Although shoulder surgery can be conducted in the lateral decubitus position, the majority of surgeons in the United States use the sitting or beach chair position (BCP).[1] In 2005, Pohl and Cullen published a 4-patient case series describing catastrophic cerebral ischemia in patients undergoing shoulder surgery in the BCP.[2] This series has prompted investigators to study how intraoperative management factors (blood pressure, type of anesthesia) may potentially affect outcomes following BCP shoulder surgery. This review presents the current state of science regarding cerebral perfusion in the BCP.

A number of investigations have used near infrared spectroscopy (NIRS) or cerebral oximetry to examine the effect of the BCP on oxygen supply to the brain. Near-infrared spectroscopy is a non-invasive technology that provides continuous monitoring of regional cerebral oxygen saturation (rSO_2). Several investigations have demonstrated that significant decreases in rSO_2 (cerebral desaturation event (CDE), typically defined as a reduction in rSO_2 of ≥20% from baseline values) are not infrequent during BCP surgery. In 2009, Fischer reported the use of NIRS to measure rSO_2 in a 63-year-old female undergoing shoulder surgery in the BCP. After induction of general anesthesia (GA) and patient positioning, hypotension was observed along with a significant decrease in rSO_2.[3] In 2010, 2 similar cases were reported in which a reduction in mean arterial pressure (MAP) precipitated a decrease in rSO_2.[4] In a direct comparison of the effect of position on rSO_2, Murphy evaluated 124 patients under GA during shoulder arthroscopy. Sixty-one patients were in the BCP and 63 in the lateral decubitus position (LDP). The incidence of CDEs was significantly higher in the BCP (80.3% vs. 0% in LDP). An association between CDE and postoperative nausea and vomiting was also observed.[5] In an evaluation of 20 consecutive patients undergoing shoulder surgery in the BCP, Moerman again found an 80% incidence of CDE associated with the BCP.[6] Tange evaluated 30 patients undergoing shoulder surgery in the BCP under GA. All patients had a normal preoperative rSO_2 and MAP. In contrast to the previous studies, no change in rSO_2 was observed intraoperatively, even during periods of hypotension leading authors to conclude that the BCP did not alter rSO_2.[7] The absence of significant decreases in rSO_2 in this study may have been attributable to the degree of sitting position used (30-60°) or the short period of observation (5 min). Furthermore, while rSO_2 is a simple and easy to use surrogate for cerebral blood flow (CBF), it may underestimate malperfusion events. Jeong compared rSO_2 with jugular venous bulb saturations in 56 patients undergoing general anesthesia with either propofol/remifentanil or nitrous/sevoflurane. This study found that cerebral oximetry had only a 30%

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Publication	Study Design	Outcome Measure	Results
Fischer et al *Pain Pract* 2009	Case report 63 yo – ASA 3	$S(ct)O_2$	↓$S(ct)O_2$ correlated with ↓MAP, ↓$etCO_2$
Dippmann et al *Arthroscopy* 2010	Case report 1) 46 yo-ASA 1 2) 58 yo-ASA 2	$S(ct)O_2$	↓$S(ct)O_2$ correlated with ↓MAP
McCulloch et al *Anaesth Intensive Care* 2010	TCD supine v. 45° beachchair (n = 19)	MCA_v	SBP_{arm} 142 → 96 mm Hg SBP_{eam} 141 → 76 mmHg MAP_{eam} 95 → 50 mmHg (47% ↓) MCA_v 46 → 36 cm/sec (22% ↓)
Lee JH et al *Athroscopy* 2011	$S(ct)O_2$ supine v. beachchair (n = 27)	$S(ct)O_2$	MAP_{eam} 85 → 75 mm Hg $S(ct)O_2$ 74 → 67%
Jeong H et al *Acta Anaesthesiolo Scand* 2012	$S(ct)O_2$ and $SjvO_2$ supine v. 65-70° beachchair w/ propofol / remi (P/R) v. sevo / N_20 (S/N) (n = 56)	$S(ct)O_2$ and $SjvO_2$	MAP_{eam} goal w/in 20% baseline. MAP_{eam} < 20% baseline: P/R grp – 69%; S/N grp – 38% $SjvO_2$ < 50%: P/R grp –56% ; S/N grp – 21% P/R anesth (OR 4.76) MAP_{eam} < 50 mmHg (OR 3.85) (p=0.02) $S(ct)O_2$ > 20% ↓ from baseline: P/R grp – 28%; S/N grp – 25% ($S(ct)O_2$ sensitivity and specificity for detecting $SjvO_2$ < 50% was 30.4% and 75.8%)
Gillespie et al *J Bone Joint Surg Am* 2012	EEG supine v. 60° beachchair (n = 52)	EEG	MAP/ SBP goal < 20% below baseline and SBP > 90 mm Hg. All pts fell below BP goals. 3 pts w/ EEG ischemia

$S(ct)O_2$,cerebral oximetry saturation; MAP, mean arterial pressure; SBP, systolic blood pressure; TCD, transcranial Doppler; MCAv, middle cerebral artery velocity; eam, external auditory meatus; P/R, propofol/remi group; S/N, sevoflurance/N_20 group.

Current Studies Warrant Caution with Hemodyamic Management of Patients in the Beach Chair Position

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sensitivity for detecting a jugular venous saturation <50% which is typically considered a critical value. Although it raises questions regarding the sensitivity of rSO_2, this study clearly demonstrated cerebral malperfusion events in the BCP with 41% of patients suffering a jugular venous bulb desaturation.[8]

It is possible that cerebral perfusion may be better maintained during BCP surgery if regional anesthesia (RA) is used. In order to investigate this issue, Yadeau performed a study using NIRS in patients receiving RA for surgery in the BCP. Ninety-nine patients were monitored continuously using cerebral oximetry. Despite a relatively high incidence of hypotension (77%), cerebral desaturation occurred in only 0.77% of patients.[9] In another observational trial, Murphy evaluated 60 patients undergoing shoulder surgery in the BCP with either GA or RA. The GA group had significantly more CDEs (57.6%) than the RA (0%) group.[1]

In conclusion, investigations using cerebral oximetry have reported that significant decreases in rSO_2 are common in the BCP when GA is used, but are rare under RA. However, in the same studies, no cerebral vascular events (CVE) leading to gross neurologic injury were identified. Further data are needed to determine the clinical significance of these CDEs. It is possible that more subtle neurocognitive injury may occur when CDEs are prolonged.

At the present time, the incidence of stroke or significant cerebral injury remains poorly defined. Friedman attempted to answer this question in a large, retrospective survey study of 93 orthopedic surgeons specializing in shoulder surgery. The overall rate of CVE was reported as 8/274,225 or 0.00291%. All 8 cases were in the BCP. The type of anesthesia was not reported.[10] In a mixed prospective/retrospective case review of 4,169 patients undergoing shoulder surgery in the BCP under RA (95.7%), Yadeau found a similarly low incidence of CVEs, reporting no events despite significant and frequent hypotension.[11] More recently, a large retrospective review evaluated 15,014 patients over an 11-year period. All patients underwent shoulder surgery in the BCP under RA. Only one new neurologic deficit was reported occurring 24-hours after surgery.[12] These large database reviews suggest a very low incidence of CVE in this population, at least when surgery is performed under RA.

Despite the low incidence of catastrophic neurologic events in the BCP, the effect of low blood pressure on CBF in the sitting position remains a concern. Several studies evaluated the effect of controlled hypotension in the BCP on CBF. Caution should be used when interpreting these studies. To date, a standard definition of hypotension does not exist. In addition, the location of blood pressure measurement is important (external auditory meatus (EAM) versus arm; non-invasive blood pressure or arterial line) as blood pressure measured at the arm may not be an accurate reflection of cerebral pressure. Lee prospectively investigated 28 patients under GA and noted that when a MAP of 60-65 mmHg (radial arterial line measured at the EAM) was maintained during surgery, a significant reduction in rSO_2 as measured by NIRS occurred (a surrogate for CBF).[13] In another study of 40 patients randomized to RA or GA, CBF was estimated using Doppler ultrasound of the internal carotid artery. BCP significantly reduced MAP in the GA group as compared to RA. Despite this, no change in CBF occurred when MAP was maintained above 70 mmHg.[14] In a similar study, McCulloch measured middle cerebral artery blood velocity using transcranial Doppler in 19 patients under GA. When hypotension was induced (SBP 142 mm Hg to 96 ± 10 mmHg at the level of the arm), a 22% decrease in middle cerebral artery blood flow velocity was noted.[15] Gillespie used electroencephalography (EEG) to monitor for cerebral ischemia in 52 patients under GA with induced hypotension in the BCP. Ischemic changes on EEG were observed in 3 of 52 patients; cerebral ischemia resolved with an increase in blood pressure. No gross deficits were noted postoperatively as measured by the mini-mental status exam (MMSE). Interestingly, the authors concluded that controlled hypotension may be tolerated safely in this population.[16] This notion is concerning for several reasons. First, a 6% risk of cerebral ischemia should not be accepted as "safe." Second, one cannot presume the "safety" of a lower blood pressure threshold when detected ischemic events prompted a change in management. Third, the sensitivity of the MMSE for the detection of neurocognitive dysfunction is poor; therefore the MMSE may fail to identify subtle post-injury sequelae of cerebral malperfusion.[17]

While these studies do not provide conclusive evidence of the harm of hypotension in the BCP, concern is raised regarding an apparent decrease in cerebral perfusion as measured by multiple modalities (EEG, NIRS, Doppler). This concern is magnified by a high incidence of antihypertensive medication use in the American surgical population. Trentman, in a retrospective chart review of 384 patients in the BCP, identified an increased incidence of hypotensive episodes and vasopressor use in patients taking antihypertensive medications preoperatively.[18] Possible mitigating techniques include the use of RA and or sequential compression devices (SCDs). Kwak evaluated 66 patients undergoing shoulder surgery in the BCP. The incidence of hypotension was slightly higher in patients who were not wearing SCDs.[19]

There is clearly a growing body of literature addressing cerebral perfusion in patients undergoing shoulder surgery in the BCP (see Table 1). Some inferences can be made from the current level of data. First, cerebral malperfusion appears to occur frequently during shoulder surgery in the BCP. The incidence appears to be greatest in patients under GA with relative hypotension. RA may protect cerebral perfusion by better maintaining cerebral autoregulation. The incidence of catastrophic neurologic injury appears to be low, but to date there are no studies evaluating more subtle forms of neurologic injury. Clinicians should be aware that blood pressure measured at the level of the arm likely overestimates cerebral pressure in the BCP. Finally, one should carefully consider a patient's baseline blood pressure when determining an "adequate" pressure to maintain cerebral perfusion. Large clinical studies are underway and should offer more information regarding the risk of shoulder surgery in the BCP and possible clues toward a best practice in managing these patients.[20] However, a "best practice" will be difficult to define until we are able to better understand the definition of baseline blood pressure and to what degree a deviation from baseline is safe. In the interim, clinicians should remain aware of the potential danger of cerebral malperfusion in this patient population.

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Beach Chair Position Requires Caution

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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.

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Dear SIRS,

Our anesthesia department recently changed to Vital Signs breathing circuits for both adult and pediatric patient populations. There was no noticeable difference between our previous supplier and the Vital Signs circuit for adult circuits. However, a major change in design was noted with the pediatric circuit. When the elbow was removed from the terminal "wye," it was discovered that the pediatric Vital Signs circuit has an outside diameter of 19 mm instead of the 22 mm of our previous pediatric breathing circuit. An anesthesia provider then attempted to fit the terminal "wye" into the anesthesia mask without success immediately following extubation of the patient. The circuit is packaged with a removable elbow that fits both 15 mm and 22 mm standard fittings. However, if the elbow becomes misplaced, as in our case, the anesthesia provider did not have a means to connect the mask to the "wye." Please see attached pictures for illustration.

Figure 1. Proper fit of Vital Signs pediatric circuit with specialized elbow adapter connected to pediatric mask.

Paul Packard, CRNA
Gina Bond, CRNA
Hickory, NC

Reply from Vital Signs Devices

Vital Signs Devices appreciates the opportunity to respond to the critical observations made on our pediatric wye piece. To recap, the external terminal connection found on the Vital Signs pediatric wye is not a 22 mm fitting, but instead is a 19 mm fitting.

ISO 5356 (2004) for conical fittings directs breathing circuit components to employ either a 15 or 22 mm but does not require fittings to be present on both the internal and external surfaces on a component. The Vital Signs pediatric wye piece uses the 15 mm internal connection.

For the external diameter, we looked at the use case for the product noting how the anesthesia breathing circuits were oriented, in general terms, parallel to the supine or prone patient. Linear components, like an HME or gas sampling adapters are functional extensions of the wye continuing the circuit's parallel orientation. A 90° connector like an elbow reorients the connections to accommodate patient interfaces like the facemask, which by design

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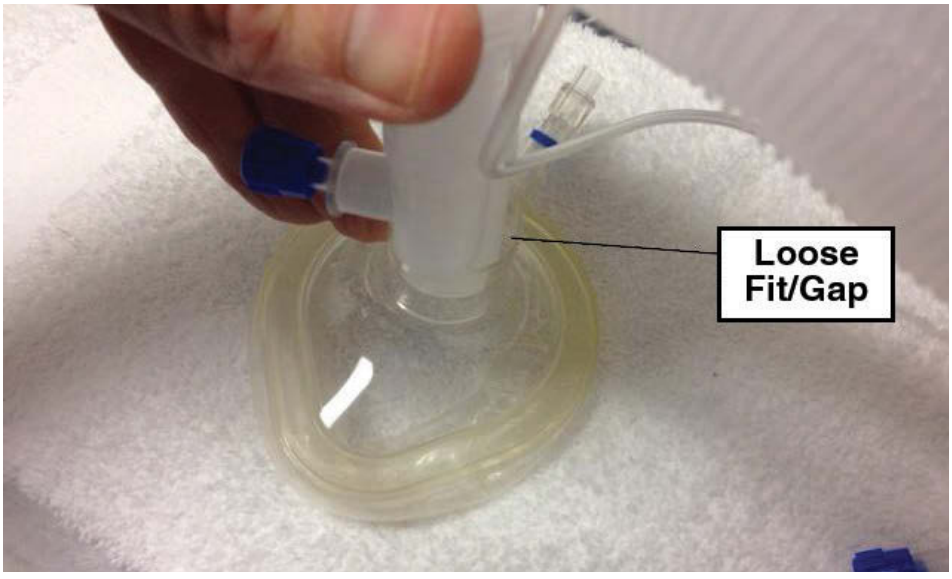

Figure 2. Superior view of loose fit of Vital Signs pediatric circuit to pediatric mask without specialized elbow adapter.

Device Manufacturer Describes Reasons for Design Changes and Welcomes Feedback on Impact to Users

"Dear SIRS," From Preceding Page

seal against the patient at a perpendicular angle to their connections. Attaching a facemask with 15 or 22 mm connection directly to the fixed wye's internal or external patient connection would result in a vertical orientation for the distal portion of the circuit tubing, wye piece and any other inline component (e.g. HME). This orientation and the resulting torque on the facemask would make it difficult to obtain and maintain a seal between the facemask and patient. Vital Signs Devices made the determination during the design phase of the pediatric wye to prevent this orientation on the wye, thus preventing direct connections to the mask.

In addition, pediatric circuits use a 15 mm tubing set and components that are smaller in dimension, often have a more compact profile, and tend to have lower dead space. Our pediatric wye piece was designed with a focus towards "minimizing" where possible. We reduced the external dimensions of the wye connection to improve the clinician's view of the patient. Reducing the external dimension also reduced the wye piece's weight. Lower weight components would tend to place less downward force on what is typically an uncuffed ET Tube. As well, smaller components also mean less to dispose of after the case.

The combination of the above factors all weighed in our previous design decisions. However, we understand your ideas about gaining redundant connection options in the event that an elbow is misplaced during a procedure. We are constantly striving to improve our product's design, functionality, and safety, and as such will give consideration to the addition of the 22 mm connector on the external surface of the pediatric wye piece during the next tooling redesign.

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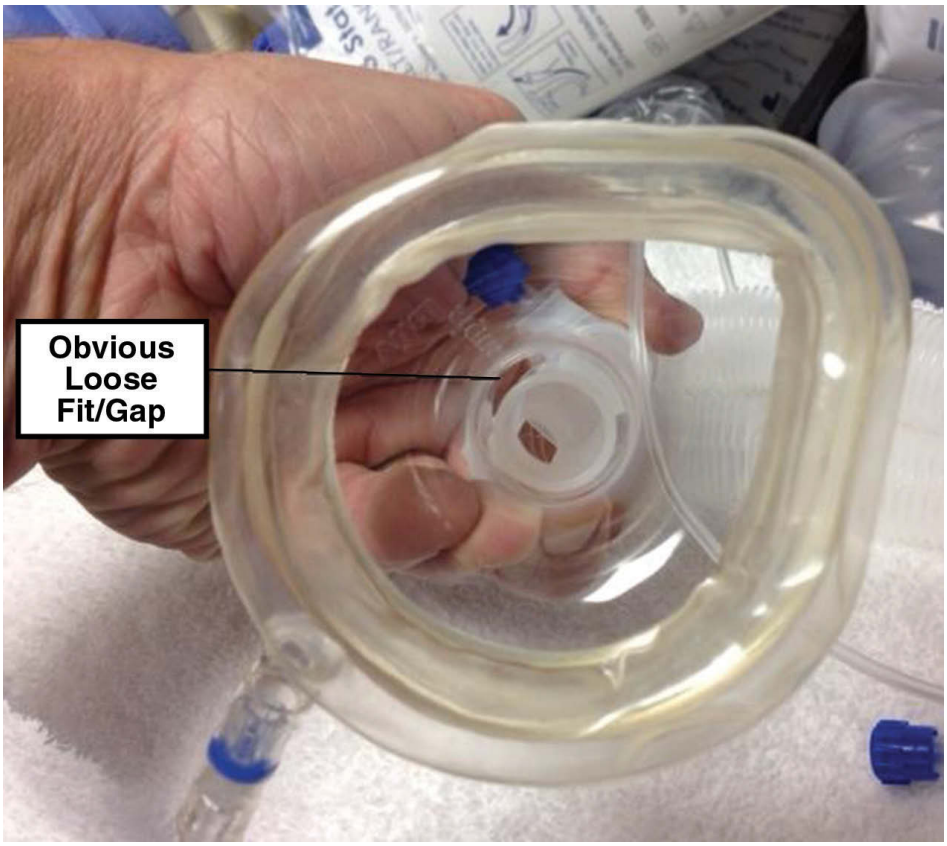

Figure 3. Inferior view of loose fit of pediatric circuit to adult mask without specialized elbow adapter.

On the Tipping Point of Disaster: Operating Room Surgical Table Tips With Obese Patients

by Shervin Razavian, MD, and John Thurn, MD

Introduction

The field of anesthesiology has experienced significant advancements and enhancements to patient safety, the result of which has been an improvement in perioperative morbidity and mortality for our patients.[1,2,3] Specifically, Gaba[2] cites several factors including a higher caliber of anesthesia staff, the need to reduce malpractice insurance costs, and anesthesiologist desire to study and improve upon patient safety outcomes as catalysts for significant patient safety improvements. These improvements include, but are not limited to, closed malpractice claims analysis, technologic solutions for improved patient monitoring, engineered safety devices to physically prevent errors from being made, the adaptation of standards and guidelines to improve patient safety, and the formation of the Anesthesia Patient Safety Foundation to further institutionalize safety in the field of anesthesia. Despite the implementation of the aforementioned patient safety features, as well as other safeguards, Staender and Mahajan[3] estimate the incidence of minor anesthesia-related perioperative events to be around 18-22%, while more severe perioperative events tend to occur at a rate around 0.45-1.4%, and events involving complications with permanent damage to occur at rates close to 0.2-0.6%. This said, despite the major advances in anesthesia patient safety, there is still significant room for improvement to enhance our patients' safety. To this end, we describe the case of a 148-kg patient who was scheduled for endoscopic sinus surgery to remove a skull-base tumor, examine the factors behind the event that almost led to significant and permanent injuries to her, and provide recommendations to prevent this from happening to future patients.

Case

Our patient, J.M., was scheduled for endoscopic sinus surgery to remove a skull-base tumor. Examination of her medical records showed the patient to be morbidly obese at a weight of 148 kg and BMI of 48.02. Further, her records showed that she had recently undergone a similar surgery with no significant perioperative complications or events noted. Pre-medication was given and the patient was transported to the operating room, where upon arrival she was able to self-transfer to an Amsco 3085 SP surgical table (STERIS Corporation Montgomery, Alabama), configured in reverse orientation given the planned surgical approach. After the placement of patient monitors per standard ASA guidelines, the patient underwent an uneventful intubation. After the placement of an arterial line and 2 additional peripheral IV lines, the surgeon requested that the patient, now intubated and under general anesthesia, be rotated 90 degrees clockwise to facilitate the surgical approach. The anesthesia circuit was disconnected from the patient's endotracheal tube and the patient's bed was unlocked in preparation for rotation. Upon unlocking the patient's bed, however, the surgical table started to tip, and the patient's head was rapidly approaching the ground. Fortunately, the anesthesia resident at the head of the bed was able to grab hold of the head of the surgical table and prevent the patient from hitting the floor. Subsequent to this, additional operating room staff were summoned to the operating room and with the help of several individuals providing support, the patient was positioned as requested by the surgeon. After an adjustable stool was placed under the head of the surgical table to serve as additional support, she underwent the scheduled surgery with no further significant complications.

Discussion

The aforementioned event piqued our curiosity as to whether similar events have been reported in the literature; however, we were only able to come across a few anecdotal reports of similar, but not identical, events occurring in operating rooms.[4] Further, while operating room surgical safety checklists, such as the oft-used and frequently cited WHO surgical safety checklist, have been shown to decrease perioperative morbidity and mortality, there is no specific mention of the surgical table in this checklist.[5] Upon discussion with our colleagues, however, it was noted that a strikingly similar event had taken place just two days prior to our event. In this particular case, a 172 kg gentleman with a BMI of 52.04 was intubated and sedated on a bariatric bed; however, upon attempting to flip the patient onto the surgical table in a prone position for spine surgery (surgical table in reverse orientation due to the need for radiology C-arm access during the case), it was noted that the patient's weight was tipping the bed, which was subsequently stabilized with a support stool placed underneath the head of the bed. This surgery was completed as well with no further significant perioperative events.

Given the near-disastrous potential outcomes of the aforementioned events, we thoroughly investigated the operation manual of the Amsco 3085 SP surgical table.[6] Specific manufacturer recommendations state that the surgical table is rated to support patients up to 1,000 lb (454 kg) in the "normal" patient orientation. Further, the tables are designed to support patients up to 500 lb (227 kg) with side-tilt in the "normal" orientation, and a 500 lb (227 kg) rating applies to the "reverse" patient orientation. In

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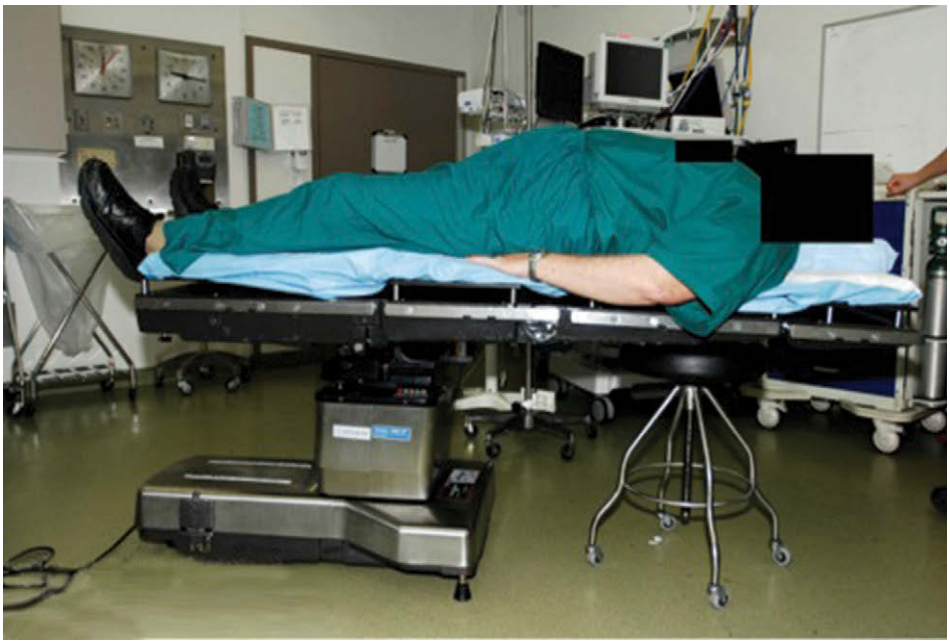

Figure 1: We enlisted the help of a colleague who weighs 160.3 kg to demonstrate the danger of OR table tipping on the Amsco 3085 SP surgical table when used in reverse orientation. Upon releasing the floor locks (with safety support present), the table tipped instantaneously.

Using Surgical Tables in Reverse Orientation Predisposes to Table Tipping

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addition, the bed is rated for patients up to 400 lb (181 kg) with the 3080/3085 Orthopedic Extension accessory, 400 lb (181 kg) with the Fem/Pop Board, and a 500 lb rating applies to Amsco Shoulder Table. Furthermore, it is stated that when performing surgery requiring a headrest accessory in a "reversed" patient orientation, one is not to exceed the 400 lb (181 kg) patient weight limit (though the headrest accessory itself weighs significantly less than 100 lb). Of interest, neither of the patients in the 2 cases we describe above exceeded these manufacturer weight recommendations. Also of note, there is no specific mention in the operator manual of patient weight ratings when the bed is "unlocked" from the operating room floor. Closer examination of the surgical table, however, does reveal a sticker near the bottom of the bed that states, "DO NOT RELEASE FLOOR LOCKS WHILE PATIENT IS ON TABLE," while showing the surgical table in the reverse orientation. Unfortunately, while not recommended by the surgical table manufacturer, the practice of releasing the floor locks of the surgical table to re-position the patient within the operating room is one that occurs frequently at the surgeon's request.

To test the potential consequences of attempting to re-position a patient within an operating room by releasing the floor locks of the surgical table while a patient is on the bed, we summoned the help of one of our colleagues, who weighs 160.3 kg. After positioning him on the surgical table in the reverse orientation (and with the help of several support personnel to prevent him from being injured), we released the floor locks of the surgical table. Almost instantaneously, the operating room table started to tip in the same fashion as our case. We documented this event in photographs and were able to see that upon releasing the floor locks of the surgical table, the tipping fulcrum of the table shifts more towards the feet of the patient, thereby enhancing the possibility of the surgical table tipping towards the patient's head. For this reason, we feel that it is absolutely necessary to comply with the manufacturer recommendation that the patient not be re-positioned within the operating room while on the surgical table, or, if it is absolutely necessary to do so, several support personnel ought to be present to help support the patient and prevent potentially disastrous outcomes. Further, it is likely beneficial to confirm orientation of the operating room table and the patient's weight with operating room and surgical personnel prior to transferring the patient onto the table.

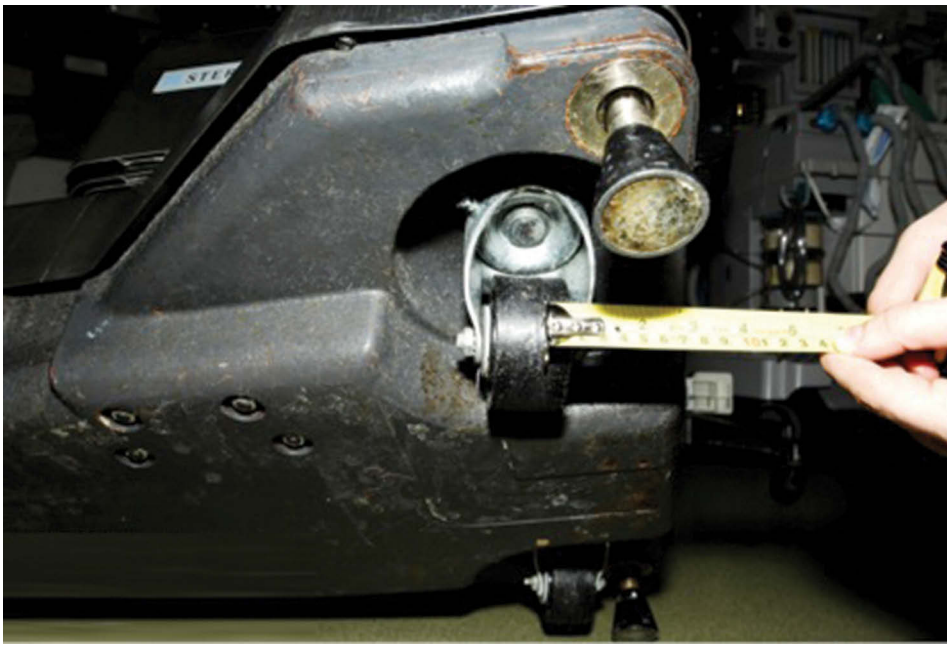

Figure 2: Note that when the OR table's floor locks are released, the fulcrum of the table shifts approximately 3 inches towards the patient's feet. While this is a small shift, it markedly changes the OR table's weight capacity and makes the table prone to tipping.

Conclusion

The field of anesthesiology has been heralded for its' many advancements in patient safety; however, significant room for improvement remains. Here, we presented a case with potentially disastrous consequences for our patient with hopes that similar events do not occur for other anesthesia providers in the future. As our population is increasingly obese and our cases more complex, it is particularly important to remain an advocate for our patients' safety despite what may be perceived to be routine practice.

The authors of this article have no financial interests to disclose with regards to this article.

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Tufts Team Develops Systematic Approach to Safe Extubation Outside of the OR

by John Adam Reich, MD, and Roman Schumann, MD

As a complement to the article by Kadis and Loskove in the Fall 2012 *ASPF Newsletter*,[1] we wish to expand the clinician's attention from the intubation of the difficult airway to the critical time of the difficult airway extubation. This is an area of patient safety that has not been addressed sufficiently in our opinion. We would like to contribute our systematic approach.

The Patient

The following case scenario was abstracted from actual patients and events that may not be unique to any one institution and serves as an illustration of the problem discussed in this report.

A 60-year-old woman presented with ischemic heart disease for emergent coronary artery bypass surgery. Following easy mask ventilation, experienced anesthesia providers were unable to intubate the patient in the operating room using standard laryngoscopy. The airway was secured with a videolaryngoscopic device and use of a bougie. After surgery, she was transported intubated to the ICU per the cardiac surgical postoperative protocol. A sign identifying her difficult airway was placed above her bed per the anesthesiology department's airway protocol for such instances. At the transfer of care to ICU team, the anesthesiologist mentioned the need to contact the anesthesiology service at the time of anticipated extubation. On postoperative day #3, she met extubation criteria and was on minimal vasopressor support. She was extubated, but developed significant respiratory distress followed shortly thereafter by cardiac arrest. The anesthesiology team responded immediately to the overhead page at the time of the code. During CPR, she could not be intubated, and the surgical airway remained a futile effort. The ICU team caring for the patient did not consult with the anesthesiology team prior to extubation on the specifics of her airway management.

The Problems

1. The assessment of risks/benefits of extubation appeared to be limited immediately prior to the event.
2. Advanced airway devices are usually not immediately available in an ICU unless specifically requested.
3. Emergency intubating conditions are often suboptimal especially during CPR.
4. Despite difficult airway identification, no additional steps were taken to prepare for potential respiratory failure after extubation.
5. Following transfer of care from the anesthesia team to a non-anesthesiology ICU team creates a high risk for loss of critical information/preparation needed at a later stage of care, in this case at the time of extubation.

Background

In 1993 the American Society of Anesthesiologists published a difficult airway algorithm that recommended a nonsurgical device (LMA, jet ventilation, or combitube) as a trial in the "cannot intubate-cannot ventilate" scenario.[2] A closed claims analysis comparing years 1985-1992 and 1993-1999 following publication of these guidelines showed a decrease in claims involving death or brain damage during induction of anesthesia. However, no similar observations could be made for airway claims relating to maintenance, extubation, or recovery from anesthesia.[3] In addition, 100% of claims originating outside of the perioperative location involved death or brain damage.[2] No information is available specifically addressing the re-intubation of the difficult airway in out-side of OR locations. In fact, in many hospitals, anesthesiology teams are part of first responders to code situations and airway management challenges for surgical and non-surgical patients alike. In these circumstances we are the first ones to identify and deal with a difficult airway. It remains our responsibility to establish a functioning mechanism to follow up with such patients that subsequently will leave our purview, to be cared for by non-anesthesiology teams in surgical and medical ICU's or step down units. Extubation is a time when airway complications can occur, and resources and expertise in ICUs may be inadequate for dealing with acute respiratory failure of a patient with known difficult airway.

Literature regarding difficult intubations is plentiful, but evidence and recommendations on tracheal extubation have been a relatively neglected area of focus.[4] Identification of a difficult airway by ID bracelet and/or inclusion with the allergy list has been useful for tracking patients throughout their hospital stay and improving safety.[1] However, as evidenced by the case above, simple identification of a difficult airway patient may not prevent poor outcomes at the time of extubation. Recently the Difficult Airway Society (DAS) has published guidelines for the management of extubation.[4] These guidelines codify an "at risk" extubation as one with a known difficult airway at intubation, an airway that may have deteriorated because of surgery, or where flexion-extension is now limited (application of halo or cervical spine fixation).[4] It is recommended that practitioners should proceed through a 4-step algorithm: 1) plan to extubate, 2) prepare to extubate, 3) perform extubation, and 4) provide post extubation care.[4] A specific requirement to consult with airway specialists prior to intended extubation to capitalize on their expertise remains unaddressed.

Preparation for any extubation should involve medical optimization of the patient to ensure success. This includes achieving cardiopulmonary stability as well as correcting metabolic derangements, normalizing temperature, and ensuring proper neuromuscular function.[4] Coordination of appropriate resources and consultations is also necessary, particularly in the known difficult airway scenario: 1) choosing location of extubation (ICU versus operating suite), 2) ensuring proper equipment availability (cricothyroidotomy kit, video laryngoscopy, fiberoptic bronchoscopy, intubating laryngeal mask airways, airway exchange catheter) and 3) ensuring appropriate staff are available (anesthesia provider-otolaryngologist).

The Solution

The clinical practice committee in the department of anesthesiology developed a pathway for extubation of patients with a difficult airway identified by anesthesia providers after these intubated patients leave the immediate purview of the anesthesiology service. The committee determined that because the patients frequently were transferred to ICUs or were intubated in offsite locations with an ICU destination determined later (cardiology catheterization laboratory, electrophysiology, CT, MRI, interventional radiology, etc.), a hospital-wide policy rather than departmental policy would be needed, and it should be applicable to adults and pediatric patients alike. Goals of the policy were to improve awareness of patients that had an "at risk" extubation, secure pre-extubation consultation with the anesthesiology service, allow for full preparedness before extubation, and accomplish safe reintubation if needed in a setting of post-extubation respiratory failure.

Difficult Airway Extubation Policy

Part 1: Identification and Communication of At Risk Extubation

After identification of a difficult airway patient who remains intubated, the anesthesia care team 1) places red stickers [Figure 1] on the endotracheal tube [Figure 2], 2) completes a bedside 8½ ×

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Hospital Develops Extubation Policy for Patients with Difficult Airways

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11 inch sign [Figure 3] to be placed above the patient's bed, and 3) places a red note in the progress notes section of the patient's chart [Figure 4], or an equivalent flag in the electronic record system. The anesthesia care team must complete all paperwork before leaving the operating room or immediately following intubation in an offsite location. Stickers and a copy of the policy are placed in all emergency code bags. Lastly the policy also requires that a physician-to-physician sign out of the case and difficult airway specifics occur.

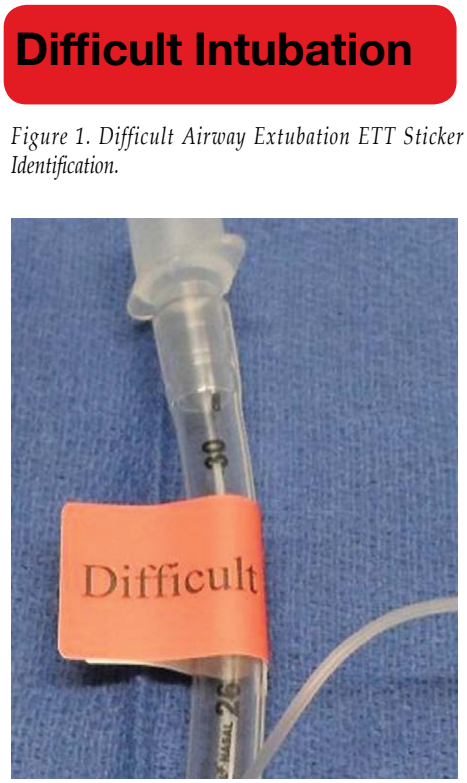

Figure 2. Difficult Airway Red Sticker Placed on ETT.

Part 2: Planning and Preparing for Extubation

Prior to the intended extubation, the policy requires that the anesthesiology department must be contacted to evaluate the patient. In addition, the patient must then be extubated in the presence of an anesthesiology member, intensivist with airway expertise, neonatologist, or pediatric otolaryngologist (the latter two being age specific). This check before intended extubation allows for proper preparation for difficult airway management. If airway difficulty or ability to oxygenate is tenuous, elective extubation in the operating room can be arranged with proper equipment and surgical teams in place.

Figure 3. 8-1/2 × 11 inch sign with description of airway placed at head of bed.

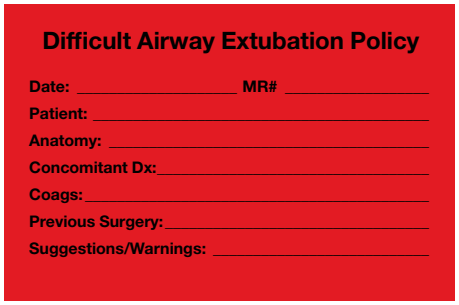

Figure 4. Difficult Airway Documentation in Progress Notes.

Has the Protocol Worked?

Since institution of the hospital-wide difficult airway extubation policy, we have had no episodes of death or inability to reintubate "at risk" airways. Another benefit has been more appreciation for safety concerns from physicians, nurses, and respiratory therapists around the "at risk" extubation.

Conclusion

Institution of a hospital-wide difficult airway extubation policy has allowed for proper preparation for extubation and improved patient safety for "at risk" extubations. While our example reflects one particular institution's approach to this issue, it calls attention to an area of airway management that is easy to lose track of within the complex, multidisciplinary hospital environment. It is our intent to encourage any health care system to establish safe approaches that will work for them to meet these difficult airway challenges in the best interest of their patients.

John Adam Reich, MD, and Roman Schumann, MD, Department of Anesthesiology, Tufts Medical Center, Boston, MA. Neither author has financial interests to disclose.

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Vision

The vision of the Anesthesia Patient Safety Foundation is to ensure that no patient shall be harmed by anesthesia.

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Mission

The APSF's Mission is to improve continually the safety of patients during anesthesia care by encouraging and conducting:

- safety research and education;
- patient safety programs and campaigns;
- national and international exchange of information and ideas.

Letter to the Editor:

The Safety of Hydroxyethyl Starch (HES)—Products Now in Doubt

To the Editor:

Hydroxyethyl starch (HES) products are commonly employed for volume resuscitation in the perioperative period as well as in ICU patients being treated for sepsis and other conditions. The rationale for their clinical use is that they are low-cost colloids that are highly effective for increasing intravascular volume for sustained periods.[1,2] Additionally, they are believed to have anti-inflammatory properties as well as other desirable characteristics, such as having a smaller impact on tissue edema compared to commonly used crystalloids.[3] As a consequence, HES products have seen a great upswing in popularity in recent years, a fact no doubt also supported by a growing number of publications offering a favorable assessment of HES products.

The purpose of this short commentary is to draw attention to some recent safety concerns for HES products. While worries about the possibility of impaired blood clotting have been a concern for some time (vide infra), more recent studies suggest that HES products are also associated with acute renal injury as well as other adverse events, including an increase in mortality. The pathophysiology may be related to the fact that HES products, while undoubtedly effective at increasing plasma volume, do not stay localized to the circulation but end up instead as deposits in renal, hepatic, splenic, endothelial, and other tissues.[4] In addition, as discussed later, HES molecules may interact with the endothelial glycocalyx in an unfavorable manner.

Evidence of the potential harm of HES products was in part diluted by a number of relatively favorable studies authored by Boldt et al., a great many of which turned out to involve scientific misconduct.[5,6] This and other considerations have led to investigators to reconsider the role of HES products, as outlined below.

A consensus statement of the European Society of Intensive Care Medicine task force on colloid use in critically ill patients, has now recommended against the use of 6% HES 130/0.4 in ICU patients.[7] Similarly, a 2011 Cochrane review cautioned against the routine administration of HES products.[8] A systematic review by Hartog et al.[9] concluded that, "There is no convincing evidence that third-generation HES 130/0.4 is safe in surgical, emergency, or intensive care patients despite publication of numerous clinical studies." The recently published 7000 patient Crystalloid versus Hydroxyethyl Starch Trial (CHEST)[10] showed that while there was no significant difference in 90-day mortality, patients randomized to HES 130/.4 had more renal injury and requirement for renal-replacement therapy than those receiving saline. Finally, a 2013 meta-analysis published in JAMA.[11] noted that after 7 tainted HES studies by Boldt et al. were removed from consideration, "Hydroxyethyl starch was associated with a significant increased risk of mortality and acute kidney injury" and warned that the "use of hydroxyethyl starch for acute volume resuscitation is not warranted due to serious safety concerns."

Although it has been known for some time that HES products can affect coagulation via adverse effects on both von Willebrand factor and platelet aggregation,[12] it is now also known that HES 130/.4 administration results in a weaker, smaller clot.[13] These facts may explain the increased transfusion rate in HES 130/.4 treated individuals with blunt trauma compared to those treated with normal saline.[14]

Finally, we would like to comment on the importance of the endothelial glycocalyx in understanding the effects of fluid administration. The endothelial glycocalyx covers the endothelial cells present in the lumen of normal blood vessels, playing a central role in its barrier properties. In conjunction with bound fluid and plasma proteins the glycocalyx forms an "endothelial surface layer," typically 500 to 1000 nm thick. The bound proteins provide the endothelial surface layer with its own colloid osmotic force, with the consequence that Starling's classic model (of semipermeable capillaries subject to hydrostatic and oncotic pressure differences) is now considered to be an oversimplification.[15,16]

The glycocalyx harbors a wide variety of anticoagulant proteins like antithrombin, components of the protein C system, and tissue factor pathway inhibitors.[17] The glycocalyx also plays a vital role in nitric oxide release in endothelial cells as well as modulating the immune response by preventing the adhesion of leucocytes and platelets to the endothelial cells.[17,18] Damage of the glycocalyx can lead to protein extravasation and tissue edema as well as impair the processes mentioned above. Continuing research on the properties of the glycocalyx and endothelial surface layer is expected to yield a better understanding of the biology of vascular permeability, inflammatory processes, blood pressure regulation, and blood coagulation, as well as clinical conditions like ARDS, sepsis and ischemia/reperfusion injury.

HES colloids have negative charges on the surface of their molecules which render them unattracted to the glycocalyx, which also has negative surface charges.[17] As a result they are unable to contribute to the integrity of the endothelium surface layer in a manner like albumin, whose distribution of positive and negative surface charges is more favorable to maintaining the integrity of the endothelial surface layer.[19]

Neither author has conflicts of interest to declare.

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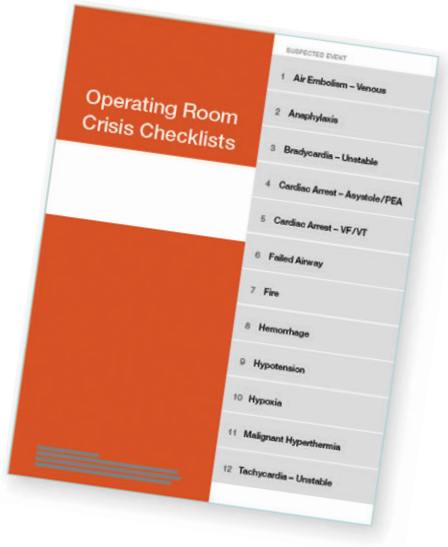

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