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NEWSLETTER

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Leading the Anesthesia Patient Safety Foundation (APSF) into the Future: Seeking Candidates for the Next APSF President

Robert A. Caplan, MD, Chair, APSF Search Committee

Robert K. Stoelting, MD, has announced that he will retire as President of the Anesthesia Patient Safety Foundation (APSF) when his next term concludes on October 22, 2016. During his 19-year tenure as APSF President, Dr. Stoelting has been a vigorous and innovative leader, dedicated to the APSF mission that "no patient shall be harmed by anesthesia."

Under Dr. Stoelting's direction, APSF has advanced the scope and impact of anesthesia patient safety by engaging a broad range of safety stakeholders in clinical practice, teaching, research, industry, and regulatory affairs. These stakeholders work together to improve patient safety with activities and products including workshops, consensus conferences, surveys, newsletters, educational videos, advisory statements, training opportunities, and research initiatives. APSF provides a vital stimulus for patient safety innovation by funding research awards and providing fellowship grants. The *APSF Newsletter*, with a worldwide circulation that exceeds 118,000, keeps the anesthesia community attuned to emerging safety concerns and new preventive strategies.

The APSF Executive Committee and Board of Directors are immensely grateful to Dr. Stoelting for the unconditional support and direction he has given to this impressive array of patient safety programs.

Search Announcement

The APSF Executive Committee has designated a Search Committee to identify qualified candidates for the next APSF President, with a term to begin October 22, 2016. The Search Committee provides the following information to interested candidates and the anesthesia community.

Robert K. Stoelting, MD, President, APSF

Position Summary

- The APSF President is the leader of the organization. In partnership with the APSF Executive Committee and Board of Directors, the President oversees all operations of the organization including strategic and financial planning, program and budget management, staff development, fundraising, external communications, and strengthening collaborative relationships throughout a diverse community of stakeholders in anesthesia patient safety.
- At present, there is no specified term or term limit for the APSF President. The Search Committee is interested in candidates who are willing to serve at least 5 years.
- Additional information, including an expanded "position summary," can be found online at www.apsf.org

Qualifications, Application Process, and Timetable

- Please see the box announcement on the outside back cover for a description of qualifications and the application process.
- On October 22, 2016, at the Annual Meeting of the APSF Board of Directors, the Search Committee will recommend a candidate for the position of APSF President.
- Immediately following approval by the APSF Board of Directors, the new President will begin his or her term.

Questions regarding the application process and/or the position of APSF President can be directed to the Chair of the Search Committee, Robert A, Caplan, MD at caplan@apsf.org.

Robert A. Caplan, MD, Chair, APSF Search Committee

ASA/APSF Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lecture

Speaker: Mark Warner, MD

Expanding Our Influence: How the Perioperative Surgical Home Will Improve Patient Safety

Annual Meeting of the American Society of Anesthesiologists

Saturday, October 24, 2015, 10:45 AM-11:45 AM
Upper Ballroom 20D,
San Diego Convention Center, San Diego, CA

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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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The Official Journal of the Anesthesia Patient Safety Foundation

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Measuring Glucose with Point-of-Care Meters: Be Careful!

by Mark J. Rice, MD, and Douglas B. Coursin, MD

Anesthesia care providers rely heavily on monitors and diagnostic devices for the safe passage of our patients. We believe that the technology we use in our practice has not only been thoroughly vetted by monitor and device manufacturers and the FDA, but also by academic physicians who have tested, compared these technologies to other systems, and published the results.

Hyperglycemia, defined in one study as 2 or more episodes of either a fasting glucose of 126 mg/dL or a random reading of 200 mg/dL, or greater, was shown to be a strong predictor of in-hospital mortality.[1] Studies such as this and others that reported changes in patient outcomes secondary to controlling perioperative glucose concentrations drove increased blood glucose monitoring in the acute care setting. In particular, the single-center intensive insulin therapy trial from Dr. Van den Berghe's group[2] reported reduced mortality (8 vs. 4.6% at 12 months) and morbidity in a surgical intensive care unit (ICU) population dominated by cardiac surgical patients. This investigation compared controlling blood glucose between 80 and 110 mgdL to a conventional treatment group (starting insulin infusions when the glucose was greater than 215 mg/dl). Ultimately, this study was shown to have limitations, but was credited with starting the wave of tight glucose control ICU algorithms, which appeared poised to engulf intraoperative glycemic management. Subsequently, a larger, multicenter, multinational NICE-SUGAR study, which was published in 2009,[3] investigated mortality in medical and surgical ICU patients by comparing a cohort with a tight glucose target of 81–108 mg/dL to a conventional goal group of <180 mg/dL. The NICE-SUGAR investigators reported an increase in mortality in the intense insulin therapy group (27.5% vs 24.9% at 90 days) and a much higher incidence of hypoglycemia. The end result of these and other well-known publications was the increased scrutiny of the methods, accuracy, and interferences with blood glucose measurement in the hospital. Furthermore, learned societies and regulatory agencies have relaxed the goals for acute care glucose manangement. The general agreement is for a perioperative glucose target <180 mg/dl and the avoidance of hypoglycemia.[4]

There are a number of options for testing blood glucose levels in the hospital including the central laboratory device (CLD), blood gas machines (BGM), and point-of-care (POC) devices. In the perioperative environment, the most commonly used system is the POC meter.[5] Until very recently these meters were the exact same devices used by patients with diabetes to measure their blood glucose at home. Although they have distinct advantages compared to CLDs and BGMs, including using very little blood volume (~5 microliters), speed of measurement (~5 seconds for testing) and being inexpensive (total direct cost ~$0.75/test), they are not nearly as accurate as CLD measurements. In addition, there are a number of interferences that are unique to these meters.[6] This review will present the overall accuracy profiles, common interferences, and recent regulation of these POC glucose meters.

POC Meter Accuracy

The commercially available POC meters use one of several enzyme systems for glucose measurements.[5] Each technology has advantages and disadvantages, but none approach the accuracy of the CLD. Furthermore, a number of drugs interfere with their accuracy (see below). POC meters most commonly use capillary blood obtained from the fingertip although arterial or venous blood is used on occasion. In comparison, CLD and BGM samples are analyzed routinely on arterial or venous blood. One of the most common errors in measurement results from sample dilution from intravenous fluid or arterial line flush. This is called pre-analytical error, and practitioners must be careful to make sure this is not the cause of unexpectedly low glucose results.

There are two important methods to express the accuracy of POC meters. The first is the Bland-Altman method, which is a difference plot with the mean of the reference and the POC device displayed on the x-axis and the difference between the two plotted in the y-axis. Figure 1 shows a typical Bland-Altman plot, with each point representing one glucose meter measurement. If all of the points were along the "0" horizontal line, the meter would agree perfectly with the reference method. The spread in values shown in Figure 1 is representative of a typical meter result. It should be noted that the Stat-Strip® is the only meter currently approved for use in critically ill patients (although it is approved only for arterial and venous blood and not for capillary sampling).

The second method commonly used to express POC meter accuracy is the Clarke error grid, which plots POC meters against laboratory reference in grids of increasing severity of the error (Figure 2). This method of data display is commonly used with POC meters to compare with CLD measurements. The severity of the error increases from A to E. Although the FDA does not rely on error grid analysis as frequently as they have in the past, the general rule is that the vast majority of the points should be in the A and B regions, with no points in the D or E regions. The A region is set so that these values are within 20% of the reference values. Obviously, a true glucose reading of 36 mg/dl that is reported as 180 mg/dl in the E zone could be fatal if insulin was administered to a patient thought to be hyperglycemic.

The accuracy profiles of the many POC meters on the market are all different. Some are more accurate in the higher glucose ranges, while others are more accurate in the lower ranges. In addition, the enzymes used in the measurements and the specific meter technologies change over time. It is therefore difficult to review historical literature and ascertain current accuracy profiles for individual meters. The same companies have different models of meters, with each having their own accuracy

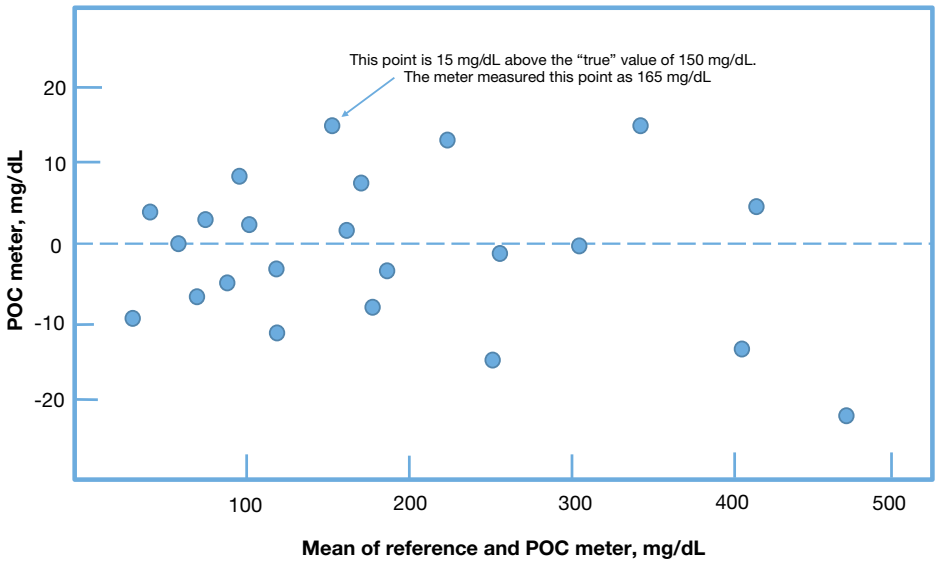

Figure 1: A hypothetical Bland Altman Plot

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Many Drugs Affect Accuracy of POC Glucose Meters

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profiles. In addition, some manufacturers are now marketing meters specifically for the hospital markets, although sometimes their technologies are similar to the meters marketed for home use.

The sample site can also influence the accuracy of a glucose result. For example, the glucose concentration is usually slightly higher in arterial than venous blood. Fingertip sampling, which is also known as capillary blood, usually yields glucose results fairly close to venous blood; however, when perfusion to the fingertips is compromised, as in either shock or with the use of vasopressors, the glucose concentration can be much lower. In general, the sicker the patient, the more careful we need to be with POC glucose monitoring[7] and it is always a good idea to send a venous or arterial sample to the central laboratory for analysis in these clinical situations.

Interferences

There are a number of drugs that interfere with many of the POC glucose meters and all have some interferences. For example, ascorbic acid, acetaminophen, dopamine, and mannitol have all been reported to significantly affect the accuracy of some POC meters. Interestingly, with the recent uptick in the use of intravenous acetaminophen for perioperative pain control, there have been no studies reporting the accuracy of meters with this possible interferent.[5]

A very dangerous interaction can be seen with the use of some older POC glucose meters and patients on peritoneal dialysis (PD). Icodextrin, which is a commonly used component of PD, is metabolized to maltose. Many of the older meters read maltose as glucose and therefore reported a falsely high glucose. A 2013 article noted the tragic case of a 65-year-old woman who was undergoing continual peritoneal dialysis. Although her POC meter readings were steady in the 150-200 mg/dL range (she received a total of 115 units of insulin in 24 hours), her actual CLD glucose values were discovered to be in the 20-40 mg/dL range.[8] She suffered a severe hypoglycemic brain injury secondary to the insulin infusion and she was discharged to a chronic care facility where care was withdrawn. Therefore, if your patient is on PD and you are using a POC glucose meter, make sure your meter is not on the list of meters that might read incorrectly. For a list of meters that should not be used with PD, see: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm attachment (accessed July 24, 2015).

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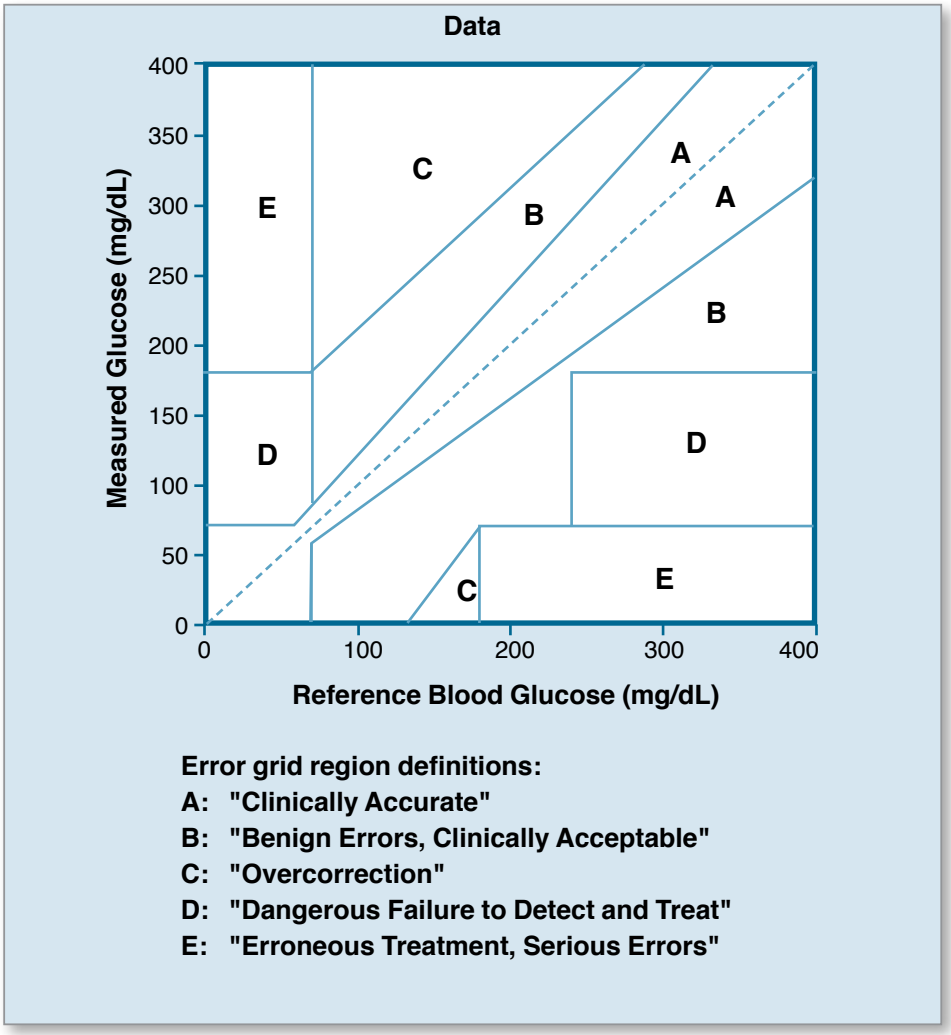

Figure 2: A Clarke Error Grid. Source: FDA Clinical Chemistry and Clinical Toxicology Devices Panel Meeting, Dec 6, 1999.

Table 1: Summary of action items for anesthesia providers for POC glucose meter use.

1.	If you suspect your POC glucose meter may be reading incorrectly, send a "stat" specimen to the central laboratory for confirmation.
2.	If the POC reading is in the hypoglycemic range, treat the patient for hypoglycemia and then send a stat specimen to the central laboratory for confirmation.
3.	If your patient is on peritoneal dialysis, make sure the POC meter is not on the list of meters that may read higher than normal (see website to the left).
4.	Capillary (fingertip) sampling may be inaccurate, especially with patients on vasopressors or in shock.
5.	Learn the accuracy and interference parameters for the meters used at your hospital.
6.	Stay tuned to the ever-changing POC glucose regulatory environment.

The Neostigmine Shortage: A Clinical Conundrum with Few Drug Alternatives

by Steven Greenberg, MD, FCCP; Sorin J. Brull, MD, FCARCSI (Hon); Pavan Rao, MD, MBA; Robert L. Barkin, MBA, PharmD, FCP, DAAPM, DACFM; Jeff Thiel, MS, PharmD; Joseph Szokol, MD, MBA, JD; and Richard C. Prielipp, MD, MBA, FCCM

Nationwide drug shortages affect anesthesia professionals every day.[1] In 2012, a survey generated by the American Society of Anesthesiologists (ASA), and accessible on the ASA website, suggested that 97.6% of anesthesiologists experienced a drug shortage in their practices. There have been several documented reasons for drug shortages, which include raw material shortages, manufacturing quality control issues, industry consolidation, and manufacturer discontinuation. Despite governmental and provider organization support to reduce drug shortages, they appear to be on the rise.[1] At the present time, no governmental agency or other entity has the accountability, authority, or responsibility to mandate a corporation or manufacturer to continue production, maintain levels of inventory and/or set prices of any drug. Drug manufacturing is a market-driven process, and pharmaceutical companies—like all corporations—must balance the needs of customers (physicians and patients), the marketplace, and shareholders. When drugs are in short supply, suspended, prohibitively expensive, or eliminated, anesthesia providers respond by searching for alternative options. However, when a drug with few alternatives becomes the focus of a drug shortage, it may significantly alter practice patterns and ultimately, patient safety.

In the previously cited ASA survey, as well as in a 2013 Survey conducted by the AANA, and accessible on the AANA website, neostigmine was one of the drugs most commonly associated with drug shortages. This shortage was in part, and interestingly, due to new U.S. Food and Drug Administration (FDA) rules. In 2011, the FDA issued revised guidance on marketed, unapproved drugs: "Compliance Policy Guide Sec 440.100, Marketed New Drugs Without Approved NDAs or ANDAs (CPG440.100)."[a] The FDA guidance established "an orderly approach for removing unapproved drugs from the market." In 2013, Eclat Pharmaceuticals, the only makers of "FDA-approved" neostigmine (Bloxiverz)[b] sent a letter calling on the FDA to stop all 5 of its competitors (Cardinal Health, West-Ward Pharmaceuticals, Fresenius Kabi USA, American Regent and General Injectables & Vaccines) from selling the "FDA-unapproved" generic neostigmine.[c] In this letter to the FDA, Eclat Pharmaceuticals also claimed that the manufacturers of unapproved neostigmine "lack complete labeling and pose a potential safety hazard." Flamel Technologies, which acquired Eclat Pharmaceuticals in 2012, significantly raised the price of Bloxiverz, the only available neostigmine preparation.[d] In the current marketplace in 2015, neostigmine is only manufactured by 2 companies (Fresenius Kabi and Eclat Pharmaceuticals),[e] which significantly increased the cost of the drug. More importantly, the shortage created a clinical conundrum for anesthesia providers because alternatives to neostigmine are quite limited. Institutions and providers across the United States may need to decide between the following choices to provide effective perioperative clinical care:

1. Continue using neostigmine at a much higher cost
2. Minimize "waste" of neostigmine by using prefilled syringes with fixed volumes/doses
3. Consider an alternative like edrophonium (with premixed atropine), called "Enlon Plus"
4. Minimize or eliminate use of NMB drugs, and thus nullify the need for reversal agents altogether.

These choices, however, may be associated with substantial unintended consequences. The unexpected increase in neostigmine pricing may create considerable financial pressure on the OR pharmacy and anesthesiology budgets. Perhaps a better alternative is to minimize the waste of neostigmine by placing it in prefilled syringes, which facilitates a more cost conscious utilization of the drug. The high cost of the reversal agent may also promote more conservative use of neuromuscular blocking agents (NMBAs) in the perioperative period. However, it may also raise the danger of an increase in residual neuromuscular blockade in the PACU because providers might inadvertently under-dose patients during the reversal process in an attempt to save on the cost of neostigmine.

Changing to the only available alternative product, edrophonium plus atropine ("Enlon Plus" in its premixed fashion) also may have unintended consequences. Many anesthesia providers may be unfamiliar with the dosing, pharmacokinetics ,and side effects of this combination reversal alternative. For instance, there may be an increase in the incidence of central anticholinergic syndrome with the addition of atropine to edrophonium. Moreover, patients with comorbidities (specifically cardiac) may be more susceptible to the drug-induced effects of secondary tachycardia or bradycardia sometimes observed with this premixed product. Additional education is certainly required to avoid drug errors and enhance clinician awareness of the potential adverse effects of this combination drug.

The difference in onset and offset of edrophonium (peak effect of 2–4 minutes) vs. neostigmine (peak effect of 6–10 minutes) must also be reviewed by anesthesia providers, and the administration should be timed appropriately. The recommended dose of Enlon Plus is 0.5–1 mg/kg edrophonium and 0.007–0.014 mg/kg atropine given intravenously over a minimum of 45–60 seconds.[2] The anticholinesterase effect of edrophonium lasts approximately 70 minutes (assuming normal renal function), and therefore, it is unlikely to result in reappearance of neuromuscular block ("re-curarization") with the intermediate acting modern muscle relaxants.[2] To make it easier for clinicians, the solution is 10 mg/mL of edrophonium, and the dose range is from 0.05–0.1 mL/kg. Therefore, a 70-kg patient would typically receive 3.5–7 mL of the Enlon-Plus mixture. Lastly, the long-term availability of edrophonium is not entirely clear, particularly if the prices of "FDA-approved" neostigmine preparations start decreasing.

Edrophonium is not as effective as a reversal agent as neostigmine, because the bonds it forms to acetylcholinesterases are mostly ionic, rather than the more resistant covalent bonding of neostigmine. Thus, if edrophonium is used for reversal of neuromuscular block, the clinician should wait for sufficient spontaneous recovery (Train-Of-Four (TOF) count of 2–3) prior to reversal. Once this level of recovery is attained, the full dose of 1 mg/kg edrophonium should be administered over at least 3–5 minutes. It should be recognized that the faster the administration, the greater the peak plasma concentration of edrophonium/atropine, so the greater the potential for

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a. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm270834.htm. Accessed Aug 7, 2015.
b. http://bloxiverz.com. Accessed August 8, 2015.
c. http://www.fdanews.com/ext/resources/newsletters/Sample-PDFs/WDL091613web.pdf
d. http://www.bloomberg.com/article/2015-01-15/aRDS4F8u8pEs.html
e. http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1150

Neuromuscular Blockade Reversal with Edrophonium Requires Change in Practice

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side effects. In patients at risk of bradycardia (elderly, pediatrics, patients on beta-blockers, etc.), the clinician should consider giving some additional atropine upfront. If TOF count is 4, and there appears to be no fade to TOF stimulation assessed subjectively, only 25%–50% of the full dose should be administered again, over at least 3–5 min.[3]

A final strategy to avoid the high cost of neostigmine is to refrain from using reversal agents altogether—the obvious concern with this choice is the high likelihood of residual neuromuscular blockade and its associated negative effects.[4] A preferred alternative would be to monitor neuromuscular function objectively (by using an accelerograph or the integrated kinetomyograph) or at least with the use of a nerve stimulator in the TOF mode. Then, choose an appropriate reversal dose based on the degree of neuromuscular recovery.

While the dilemma of neostigmine shortage and high pricing highlights the impact of drug shortages on practice patterns, it will not be the last one. In the 2015 February issue of the *APSF Newsletter*, Orlovich and Kelly wrote a concise review on the drug shortage issue as it relates to anesthesia providers. They offered several factors and potential solutions to proactively prevent the ever-increasing anesthesia drug shortage epidemic.[5] It is up to anesthesia organizations, business leaders, hospital administrators, and government officials to rethink viable solutions to this ever growing problem, so that our patients do not assume unnecessary perioperative risk. Lastly, but perhaps most importantly, Hsia et al. recently suggested that a clear majority of patients (60.9%) want to be informed of a drug shortage even if it made little difference to patient outcomes.[6] On the other hand, informing patients of the shortages may increase their fear and anxiety unnecessarily, just prior to surgery, and therefore this disclosure needs to be reviewed carefully and critically. However, it may allow us, as providers, to stop and appreciate that our patients are becoming more concerned and knowledgeable about their care and the ever-escalating problem of drug shortages. This may be the right time to enhance our alliance with our patients and help lobby for effective changes to curb this recurring problem. Meanwhile, we must continue to prioritize patient safety and value-based care.

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Editorial Note: In a 2013 survey conducted by the AANA, 48.6% of respondents reported a neostigmine shortage as well.

References:

1. De Oliveira GS, Jr, Theilken LS, McCarthy RJ. Shortage of perioperative drugs: implications for anesthesia practice and patient safety. *Anesth Analg* 2011;113: 1429-35.
2. Cronnelly R, Morris RB, Miller RD: Edrophonium: Duration of action and atropine requirement in humans during halothane anesthesia. *Anesthesiology* 1982; 57: 261-6.
3. Thilen SR, Hansen BE, Ramaiah R, Kent CD, Treggiari MM, Bhanaker SM. Intraoperative neuromuscular monitoring site and residual paralysis. *Anesthesiology* 2012;117: 964-72.
4. Murphy GS, Brull S. Residual neuromuscular block: Lessons unlearned. Part I: definitions, incidence, and adverse physiologic effects of residual neuromuscular block. *Anesth Analg* 2011;111: 120-8.
5. Orlovich DS, Kelly RJ. Drug shortages in the US - A balanced perspective. *APSF Newsletter* 2015;29: 49-50.
6. Hsia IKH, Dexter F, Logvinov I, et al. Survey of national drug shortage effect on anesthesia and patient safety: A patient perspective. *Anesth Analg* 2015;121: 502-6.

Letter to the Editor:

Chlorhexidine Can Cause Allergic Reaction

The use of chlorhexidine is recommended in various clinical settings secondary to its activity against a broad range of organisms. Chlorhexidine is present in different preparations not only as a skin and surgical disinfectant, but also in cosmetics and several pharmaceutical products. Diverse hypersensitivity reactions to chlorhexidine have been described, comprising allergic contact dermatitis, stomatitis, urticaria, dyspnea, and anaphylactic shock. Several cases of chlorhexidine anaphylaxis under anesthesia have been reported with the incidence reported as increasing. Since chlorhexidine is commonly used as skin disinfectant before surgery or invasive procedures, the potential for developing an allergic reaction to chlorhexidine may be significant, especially under anesthesia.

The true incidence of chlorhexidine allergic reactions remains unknown precisely. Anaphylaxis during surgical and interventional procedures may be difficult to evaluate because of the rapid, successive use of multiple drugs. Awareness to this potential problem, including detailed history, testing for chlorhexidine allergy in patients with suspected allergic reaction, and preparedness to treat serious allergic reactions is recommended.

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References:

1. Liippo J, Kousa P, Lammintausta K. The relevance of chlorhexidine contact allergy. *Contact Dermatitis.* 2011;64:229-34.
2. Nagendran V, Wicking J, Ekbote A, Onyekwe T, Heise Garvey L. IgE-mediated chlorhexidine allergy: A new occupational hazard? *Occupational Medicine* 2009;59:270-2.
3. Garvey LH, Roed-Petersen J, Husum B. Anaphylactic reactions in anaesthetised patients—four cases of chlorhexidine allergy. *Acta Anaesthesiol Scand* 2001;45:1290-4.
4. Nakonechna A, Dore P, Dixon T, Khan S, Deacock S, Holding S, Abuzakouk M. Immediate hypersensitivity to chlorhexidine is increasingly recognised in the United Kingdom. *Allergol Immunopathol (Madr)* 2014;42:44-9.
5. Garvey LH, Krøigaard M, Poulsen LK, Skov PS, Mosbech H, Venemalm L, Degerbeck F, Husum B. IgE-mediated allergy to chlorhexidine. 2007;120:409-15.
6. Abdallah C. Perioperative chlorhexidine allergy: Is it serious? *J Anaesthesiol Clin Pharmacol* 2015;31:152-4.

Obstetric Anesthesia Patient Safety:

Practices to Ensure Adequate Venous Access and Safe Drug Administration During Transfer to the Operating Room for Emergency Cesarean Delivery

by Rachel M. Kacmar, MD, and Jill M. Mhyre, MD

On behalf of the Society for Obstetric Anesthesia and Perinatology (SOAP) Patient Safety Committee

Patient transfer to the operating room for emergency cesarean delivery is a high risk epoch for serious medication error or venous access complication, based on a series of patient safety incidents reported to the Society for Obstetric Anesthesia and Perinatology (SOAP) Patient Safety Committee. Emergency cesarean delivery can be among the most time sensitive surgical procedures performed. In the rush to the operating room, well-intentioned intraprofessional teams have the potential to make any number of skill-based errors or mistakes with serious consequences. Even minor errors, such as venous access dislodgment, can produce life-threatening delays in this context.

Magnesium sulfate and oxytocin are included in the list of high risk medications by the Institute for Safe Medicine Practices (ISMP) (Table 1). Inadvertent bolus administration at the time of transfer to the operating room may be caused by pump programming errors or confusion between magnesium sulfate, oxytocin, and intravenous (IV) fluids used for hydration.[1] Strategies for safe use of both magnesium and oxytocin are actively investigated. Medication administration on an infusion pump through dedicated, color-coded tubing without stopcocks or side-injection ports can reduce the risk of drug error. This facilitates a process by which the color coded tubing may then be rapidly disconnected from the main intravenous line, and capped, prior to emergent transfer to the operating room (Table 2).

Venous Access

Although many delivery units require minimum gauge venous access (e.g., 18 gauge),[2] (Table 3), some patients refuse intravenous (IV) cannulation or present access difficulty resulting in smaller gauge IV placement. Patients should be counseled regarding the role of IV access during emergency care and the potential for worsened outcome should delivery or resuscitation be delayed due to lack of sufficient venous access. In patients who do not require or refuse IV fluids during labor, a heplocked IV can be placed to provide emergency access if needed. This can be covered with a water-tight occlusive dressing (e.g., Tegaderm) for parturients who wish to utilize a shower or birthing tub during labor.

Increasingly, units rely on infusion pumps to administer all fluids and medications during labor. Infusion pumps have the potential to mask IV infiltration, which is only recognized at the time of transfer to the operating room. To verify patency, teams should be trained to critically examine the insertion site at regular intervals, and to remove the carrier solution from the infusion pump to verify successful administration by gravity prior to transfer to the operating room (Table 2). To facilitate more rapid transfer to the operating room, and to limit the risk of dislodgement, the main carrier line can either be disconnected and capped, or clamped off, and positioned alongside the patient in the bed immediately adjacent to the intravenous insertion site.

With some infusion pump systems, the intravenous tubing does not contain injection ports, or does not allow flow when disconnected from the infusion pump. As noted, these are desirable characteristics for the tubing used to administer high risk medications, but mandate tubing replacement prior to OR transfer for the main carrier line. Systems to facilitate rapid tubing replacement include assigning the responsibility to the anesthesia providers, advanced preparation of a tubing setup in the operating room keeping in compliance with United States Pharmacopeia chapter 797 for Pharmaceutical Compounding—Sterile Preparations,[3] and widespread distribution of the equipment to prepare additional tubing setups. As health systems look increasingly towards efficiency and cost containment, tubing systems that function across clinical contexts will become increasingly important, and anestheisa professionals who engage with hospital equipment purchasing committees may be successful in identifying and selecting products that obviate the need to switch tubing altogether. To maximize equipment familiarity, the same type of IV tubing and infusion pumps should be utilized in all anesthetizing locations within an institution.

Infusion pumps are heavy and once multiple infusions are started, pose the risk of tangled lines and the need for additional equipment to hold the pump(s). Depending on the medication and indication, infusions often need to accompany the patient to the operating room. Epidural and intravenous infusion pumps loaded with medication solutions and capped tubing can be hung on a single IV pole, and transported to the operating room by any provider who is not simultaneously maneuvering the patient and bed *(Table 2 and Table 3)*. This process helps prevent lines from further tangling, lines from being run over by the patient's bed, and potential loss of an IV if the pole and infusion lines get caught on a door frame. Having infusions disconnected during transit for an emergency case also helps protect from accidental

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Disconnect High Risk Medication Infusions During OB Emergency Transport

"OB Emergency Transport," From Preceding Page

changes in drug administration by rushed care team members. For elective or urgent cesarean deliveries when there is additional time to prepare, good communication is needed between the anesthesia, obstetric, and nursing teams regarding whether or not to disconnect infusions during transport.

Management of Magnesium Infusions

Magnesium sulfate is indicated to reduce the risk of eclampsia in women with preeclampsia with severe features[4] and also for neuroprotection for fetuses at less than 32 weeks estimated gestational age.[5,6] According to one commonly recommended protocol for preeclampsia, a bolus of magnesium sulfate (4–6 grams) is followed by a continuous infusion (1–2 gram/hr),[7] and the patient's deep tendon reflexes are monitored for signs of early magnesium toxicity. Magnesium is considered a high risk medication due to the potential for sedation, respiratory depression, arrhythmia, and even cardiac arrest if given in excess.[8-10] Accidental overdose of magnesium resulting in cardiac arrest has been reported during transport of a parturient to the operating room for emergency cesarean delivery.[9] Magnesium sulfate also prolongs the duration of nondepolarizing neuromuscular blockade and bolus administration is a risk factor for uterine atony. Current American College of Obstetricians and Gynecologists (ACOG) recommendations support continuing magnesium infusion during delivery, whether vaginal or cesarean, in patients with preeclampsia with severe features.[4] The half-life of magnesium is 5 hours; holding the infusion throughout a cesarean delivery may increase risk for postpartum maternal seizure.[11] Thus, while the magnesium infusion should be discontinued during transport to the operating room for cesarean delivery, the infusion should be restarted as soon as feasible before or during the surgery (Table 3). Consultation with the labor and delivery nurse may be necessary to ensure appropriate infusion pump re-programming at the time of restarting the magnesium infusion.

When magnesium is given for fetal neuroprotection, depending on the regimen, the infusion is continued 12–24 hours or until birth, whichever occurs first.[12,13] When a woman requires emergent cesarean delivery while receiving magnesium for fetal indications, there is no demonstrated benefit to maintaining the infusion to the moment of birth.[13,14] As previously mentioned, the infusion should be discontinued for transport. Due to the long half-life of magnesium, serum levels will be maintained in both mother and fetus in the short time required for emergent cesarean delivery of the infant.

Table 1: Institute for Safe Medication Practices (ISMP) High-Alert Medications† that are frequently administered on labor and delivery units.

Specific Medications
Epinephrine
Epidural or intrathecal medications
Insulin
Magnesium sulfate
Oxytocin
Nitroprusside
Potassium chloride
Promethazine

†Medications that carry increased risk of patient harm when given improperly or in error. Table adopted from www. ismp.org and patientsafetyauthority.org.

Management of Insulin Administration

Likewise, intrapartum insulin is almost always administered for fetal indications, specifically to prevent neonatal hypoglycemia. Given the imminence of delivery with emergent cesarean, insulin should be discontinued prior to transport to the operating room, without concern for significant impact on neonatal hypoglycemia (Table 3, Page 43). Maternal blood glucose management can be addressed using protocols appropriate for all postoperative adult patients.

Management of Oxytocin Administration

Oxytocin administration is particularly hazardous because appropriate antepartum doses utilized for induction and augmentation of labor are an order of magnitude less than postpartum doses needed to promote uterine tetany and prevent postpartum hemorrhage. If large doses are given prior to delivery, uterine tachysystole can occur, impeding blood flow and oxygen delivery to the placenta and fetus, and necessitating urgent or emergency cesarean delivery.[15] Because oxytocin is often infused from a 500 or 1000 mL bag, perinatal providers may mistake the oxytocin for a bag of crystalloid fluid and administer a fluid bolus in response to fetal bradycardia or maternal hypotension.[16] Ideally, commercially or pharmacy-prepared bags of oxytocin solution are supplied in IV bags with a distinct size and shape not used for any other purpose on the unit. When providers prepare IV bags of oxytocin in bags of crystalloid commonly used on the unit (e.g., 30 Units/500-1000 mL), care should be taken to circumferentially label the bag to reduce the risk of confusion with plain crystalloid solutions. Similar to magnesium, oxytocin infusions should be disconnected from the patient prior to transport to the operating room for cesarean delivery (Table3). The most conservative way to prevent premature administration is to wait to reconnect the oxytocin infusion to the intravenous line until after delivery of the infant.

Postpartum oxytocin is most commonly administered as a continuous infusion. Bolus administration and infusion rates above 1 unit/minute can result in hypotension, tachycardia, chest pain, and myocardial ischemia (e.g., ST changes on EKG, increases in troponin).[17,18] The common practice of injecting concentrated oxytocin into a standard IV crystalloid bag (30 units in 500 or 1000 mL), and running the solution "wide-open" results in uncontrolled infusions that may easily exceed 1 unit of oxytocin per minute. The optimal post-cesarean oxytocin infusion protocol has yet to be determined, but infusions of 300 milliunits per minute

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Table 2. Emergency Cesarean Transport Procedure‡

1.	Disconnect all medication infusions, leaving crystalloid only attached to the main IV tubing
2.	Cap all IV medication lines, the epidural infusion line, IV tubing stopcocks and side ports, and the epidural catheter; maintain appropriate caps at bedside (e.g., hanging from the IV pole)
3.	Remove the main IV line from the infusion pump, and administer crystalloid by gravity to verify a free-flowing infusion; for inadequate flow, secure appropriate venous access either immediately or upon OR entry
4.	During transport, position clamped IV line next to patient as close as possible to the IV insertion site to prevent inadvertent dislodgement during transport
5.	Transport all IV and epidural infusion pump(s), medication solutions, and capped infusion lines to the OR separated from patient (e.g., hanging on an IV pole).

IV = intravenous; OR = operating room; L&D = labor and delivery unit

‡Suggest training all L&D nurses to apply this procedure for any emergent transfer to the operating room.

"Extreme" Remote Locations Raise Unique Safety Concerns

by Charles E. Cowles, MD, MBA; Vianey Q. Casarez, CRNA, DNP; and John W. Wiemers, CRNA, MS

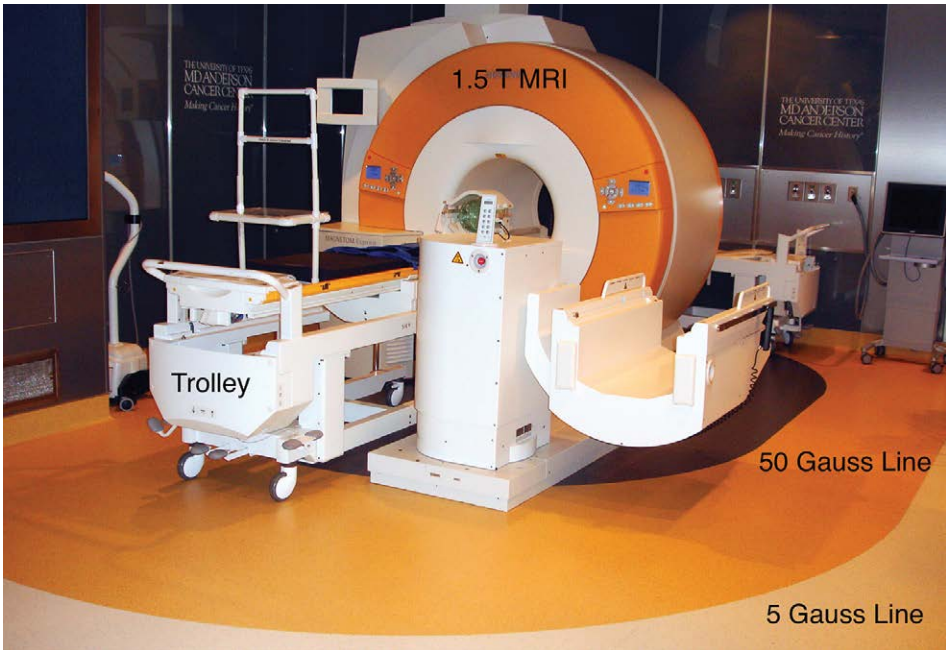
As medical technology advances, so does the complexity of the environment for anesthesia care. Many specialty care centers are utilizing hybrid combinations of MRI, radiation, and lasers in operating suites and other patient care areas. Some of these new treatment and diagnostic modalities pose hazards to the patient, anesthesia provider, and the safe delivery of an anesthetic. In this segment, we will attempt to describe the challenges met at the MD Anderson Cancer Center during the design, implementation, and utilization of new cutting-edge technologies. Since many of these facilities are located a significant distance from the main operating room suite, they are considered remote locations. However, what makes them "extreme" locations is the fact that the anesthesia provider is usually separated from the patient during treatment and that team members must understand specific safety and logistical nuances to provide a safe anesthetic for the patient.

Laser Ablation with intraoperative MRI.

Intraoperative MRI (iMRI)

Intraoperative MRI or iMRI facilities are expanding from specialty care centers to regional hospitals as their costs become more economically feasible and their uses expand. As a National Cancer Institute (NCI) designated cancer center, we began operating in the iMRI in 2007. In the iMRI, a special table interfaces with a patient in neurosurgical pins, an MRI scanner, and a navigation system. Using this integrated system, surgeons are able to scan prior to surgical incision to load image data into the navigation system to guide the surgical approach. As the surgery progresses and resection ensues, subsequent scans are obtained intraoperatively to update the data to assess tumor remnants and also to create a reference for proximity to key structures.

There are challenges to providing a safe environment for the patient and staff. Patient selection is important and is established through a questionnaire that focuses on possible ferrous containing implants such as pacemakers, metal joints, aneurysm clips, and even certain permanent make-ups and tattoos. Patient body habitus plays a factor as well, and an occasional "dry run" must occur to ensure the MRI scanner can accommodate the patient. Instrument counts are paramount before the surgery ensues and before every intraoperative scan including needle counts, so as to make certain that no instruments cross the 5 Gauss line (the outermost line that defines the limit beyond which ferromagnetic objects are strictly prohibited) and into the scanner. We utilize an induction room that is separated, by a door, from the MRI scanner environment so that during induction of anesthesia and invasive line placement, ferrous containing instruments like laryngoscope blades, handles and needles from line placement are well outside of the 5G area of protection. This induction room also serves as a designated area that houses resuscitative equipment and, in the event of an emergency, serves as an area in which cardiopulmonary resuscitation can take place safely. This room also allows for the assistance of additional personnel without exposure to the MRI environment.



Intraoperative MRI Suite showing patient trolley, 5 gauss line and 50 gauss line.

Soon after establishing a routine for craniotomies using the iMRI, our surgeons then approached the neuroanesthesiologists and requested that we provide awake neurocognitive testing in the iMRI suite. This request posed a new set of challenges. These challenges included our airway management choices, the head fixation device and coil, and our anesthetic management of these cases.

We generally provide an asleep-awake-asleep (sedated) technique for awake craniotomies. The asleep portions of the anesthetic are usually managed with a supraglottic airway. Some of these devices contain wire reinforcement in the ventilating port and caused unwanted artifacts. Airway devices free of metallic reinforcement must be used for cases in the iMRI. The head fixation apparatus acts as the inferior coil for imaging and had to be

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Patient Accessibility is Limited in Extremely Remote Locations

"Extreme Locations," From Preceding Page

modified to facilitate airway management during the wake up and awake periods of the craniotomy. We employ a balanced anesthetic technique utilizing propofol and remifentanil infusions. Because of the Tec 6 vaporizer incompatibility, desflurane cannot be used; therefore, our inhalational gas choices are isoflurane and sevoflurane. Our neurosurgeons readily call on electrophysiology colleagues to perform continuous motor mapping, cortical mapping, and EEG monitoring. The computers used for this monitoring are not MRI compatible and must be tethered to the walls to ensure that they do not cross the 5 Gauss line. Careful placement of all the additional wiring for successful mapping/monitoring is required to ensure that no formation of wire loops or coils occur which can result in thermal burns to the patient.

The iMRI suite was designed with a power system that can disconnect power to all but 1 power outlet designated for use by the anesthesia machine. As we expanded our practice to include right-sided awake craniotomy in the iMRI environment, we saw the need to move the anesthesia machine to be near the left shoulder of the patient. This required getting another dedicated power outlet for our use.

As technology advanced further, we were asked to study a system for laser interstitial thermotherapy in which a laser is used to thermally ablate tumors using real time MRI guidance and a fiberoptic laser transmission system. Neurosurgeons can use this technique of thermal ablation to ablate intracranial tumors deemed unresectable, as well as metastatic lesions of the vertebral column. During intracranial ablations, fiberoptic laser catheters are placed through burr holes and advanced to the tumor site with the use of the MRI. As the thermal ablation takes place, continuous MRI images show the neurosurgeon and neuroradiologist the extent of thermal injury through the tumor bed. Bony metastasis of the spine can be thermally ablated as well. The patient is positioned prone and a series of ablation catheters are placed within the vertebral bodies that contain the bony metastasis. During the ablation phase of the surgery, breath holding is needed to reduce the movement of the thorax. The laser used is a 30 W 980 nm diode laser with a fiberoptic. Since no laser energy is delivered unless the catheter is internalized, no special laser precautions are needed.

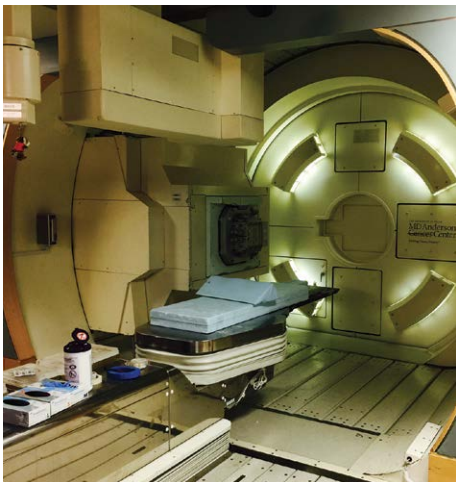
Anesthesia providers, with hearing protection in place, are required to stay in the MRI suite to control the patient's ventilation as needed for the procedure. Since any patient movement interferes with the calculations of thermal energy, breath holds of up to 100 seconds are needed. In anticipation of the breath holds, we hyperventilate the patient on 100% oxygen for a brief period prior to the requested breath holding.

Interventional MRI

MRI has become the standard modality for assessing soft tissue. Many times a small area of concern could be identified during an MRI, but the same tissue could not be identified for biopsy using fluoroscopic or CT guidance. For these situations and also for patients with tumors located precariously close to vital structures, an interventional MRI suite was created.

The procedure room is a large room with a centrally located MRI. All of the anesthesia monitors and machines are approved for MRI use. Interventional radiologists perform these procedures. For many techniques, breath holding is required so we usually perform endotracheal general anesthesia technique. Basically the same precautions are taken as for a standard MRI scan or interventional radiology procedure.

Communication among the anesthesia providers and the specialists performing the procedure is vital and creates an additional challenge. The patient is moved into the MRI for image acquisition and then removed from the bore to place the needles. The patient is then scanned again. To provide hearing protection and also to allow communication between team members, we use wired microphone headsets/ protectors which are MRI compatible.



Gantry for proton beam therapy.

Proton Therapy Center

In 2004, MD Anderson Cancer Center in Houston opened the Proton Therapy Center. Proton therapy is the directing of a radioactive proton beam targeted to administer these protons with a precision of 1 mm. As opposed to conventional radiation therapy, the use of protons allows minimal interference of healthy tissues surrounding the tumor. This becomes particularly important for tumors located near vital organs. Tumors such as deep-seated medulloblastomas, within the brain or brainstem, were not usually amenable to standard radiation treatment using linear accelerators due to risk to surrounding tissue, but now these tumors can be treated with precision using proton therapy.

Most children under the age of 6 years require anesthesia services to prevent the dire consequences that could occur as a result of patient movement during these treatments. Our practice is currently providing about 140 anesthetics per month at the proton center. Patients requiring anesthesia services are scheduled for a CT simulation appointment and then subsequent proton therapy appointments. CT simulation appointments are required prior to the initial proton therapy appointment for the development of the proton treatment plan and immobilization devices. Immobilization devices, such as masks and cradles, are created to ensure exact repositioning of the patient for each treatment. The child is anesthetized during the simulation and a custom mask is created, which is used to immobilize the head in a predetermined position. If an airway obstruction occurs or if an oral airway or supraglottic device is required, the mask must be reformed and the simulation repeated. Masks are created from plastic net molding and holes can be created for an oxygen cannula. Properly made immobilization devices are imperative because typically proton

Proton Therapy Control Room.

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APSF/AQI Patient Safety Career Development and Research Award: *Announcing the 2015 Recipient*

The APSF and the Anesthesia Quality Institute (AQI) have joined together to co-sponsor an APSF/AQI Patient Safety Career Development and Research Award. Both organizations are dedicated to improving patient safety and the delivery of anesthesia care. Specifically, their respective bylaws and mission statements include

- **AQI**: "will promote patient health and safety through the fostering of advances in quality of care measurement and improvements in the delivery of anesthesia medical care."
- **APSF:** "to improve continually the safety of patients during anesthesia care by encouraging and conducting safety research and education…"

A joint committee of the 2 organizations is pleased to announce that the recipient of the 2015-2016 award is Joseph A. Hyder, MD, PhD. Dr. Hyder is an assistant professor in the Mayo Clinic Department of Anesthesiology in Rochester, MN. Dr. Hyder obtained his MD and PhD (epidemiology) degrees from the University of California, San Diego. After an internship in Internal Medicine at the Brigham & Women's Hospital, he undertook his anesthesiology residency training at the Mayo Clinic in Rochester. He subsequently was a fellow in Critical Care Medicine at the Massachusetts General Hospital and a Research Scholar in Residence at the Brigham & Women's Hospital's Center for Surgery & Public Health. In that latter role, he worked extensively with the National Surgical Quality Improvement Program's (NSQIP) database.

Dr. Hyder's research agenda addresses definitions of surgical quality as they are used for local quality improvement and national benchmarking. His work in quality measurement includes assessing adequacy of surgical risk adjustment, evaluating complication cascades to measure quality, and investigating perioperative strategies to improve surgical outcomes. Dr. Hyder will work with the AQI and National Anesthesia Clinical Outcomes Registry (NACOR) to extend the possibilities of real-world performance measurement, aiming for performance measures that have good face value, are practical for local quality improvement, and can drive value and safety nationally.

One unique feature of the award is that Dr. Hyder will participate in meetings of the APSF Executive Committee and the AQI Board of Directors. His participation will expose him to the breadth of issues that the 2 organizations address.

Joseph A. Hyder, MD, PhD

Dr. Hyder will be asked to consider potential collaborative initiatives that the APSF and AQI might pursue together to improve patient safety and improved anesthesia delivery models.

Both organizations extend congratulations to Dr. Hyder for being the inaugural recipient of this award.

Request for Applications (RFA) for the

SAFETY SCIENTIST CAREER DEVELOPMENT AWARD (SSCDA)

Application deadline: February 1, 2016

APSF is soliciting applications for training grants to develop the next generation of patient safety scientists.

APSF will fund one ($150,000 over 2 years) **Safety Scientist Career Development Award** to the sponsoring institution of a highly promising new safety scientist. The award will be scheduled for funding to begin July 1, 2016.

Please contact Stoelting@apsf.org
to request the SSCDA GRANT GUIDELINES AND APPLICATION.

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West Florida Anesthesia Consultants
Wichita Anesthesiology, Chartered

In Memoriam

In memory of Max Berenbom, PhD (David A. Gaba, MD)
In memory of Karl K. Birdsong, MD (Texas Society of Anesthesiologists)
In memory of Harold C. Boehning, MD (Texas Society of Anesthesiologists)
In memory of Raymond Boylan, MD (Raymond J. Boylan, Jr., MD)
In memory of W. Darrell Burnham, MD (Mississippi Society of Anesthesiologists)
In memory of Raymond W. Cohen (Jerry A. Cohen, MD)
In memory of Sanjay Datta, MD (Mark C. Norris, MD)
In memory of Hank Davis, MD (Sharon Rose Johnson, MD)
In memory of Katie Donahue, DO (James Lamberg, DO)
In memory of Eugene H. Flewellen, III, MD (Texas Society of Anesthesiologists)
In memory of Margie Frola, CRNA (Sharon Rose Johnson, MD)
In memory of Andrew Glickman, MD (Sharon Rose Johnson, MD)
In memory of Donna M. Holder, MD (Karen P. Branam, MD)
In memory of Russell Morrison, CRNA (Jeanne M. Kachnij, CRNA)
In memory of Paul A. Stern, MD (Texas Society of Anesthesiologists)
In memory of Jack D. Stringham, MD (Gregory Peterson, MD)
In memory of Alon P. Winnie, MD (Frank Moya Continuing Education Programs)
In memory of Peter Y. Wong, MD (Texas Society of Anesthesiologists)

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Letter to the Editor:

An Unintended Addition to a Vial of Naropin™ 0.2%

To the Editor:

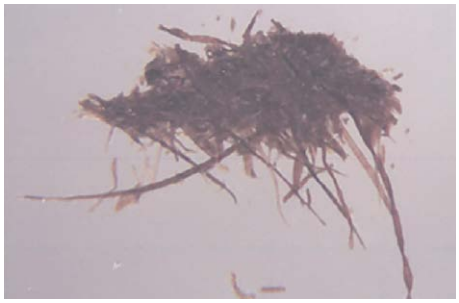
At Memorial Hermann Hospital—Texas Medical Center, a pharmaceutical contaminant was noted in a vial of Naropin™ 0.2% (APP Pharmaceutical, Fresenius Kabi, USA). Unmagnified, the object appeared to be a small insect and was withheld from epidural injection (see Figure 1). Hospital administration and central pharmacy were immediately notified, as was the manufacturer. All Naropin™ 0.2% vials from the identified lot were removed from our institution and its affiliates.

In the ongoing investigation and subsequent communication with the manufacturer, who was immediately responsive and supportive, magnified images and Infrared Spectroscopy revealed that the mass was composed of intertwined cellulose fibers (see Figure 2, 63× magnification). During the last update from the pharmaceutical company on this matter, it was not clear at which point in the manufacturing process the particular cellulose contaminant was introduced into the vial: manufacturing, sterilization, or packaging. They believe it was related to the preparation or packaging of the caps.

Recurring reports of adverse outcomes linked to contaminated pharmaceuticals have heightened concerns regarding sterility of drug supplies. The most severe recent example linked a compounding pharmacy producing methylprednisolone acetate to cases of fungal meningitis.[1]

Figure 1. The vial with the foreign object

Figure 2. Low magnification and higher magnification of the foreign object.



Given the consistent drug shortages affecting anesthesia professional, findings such as ours, particularly in light of the aforementioned contamination catastrophe, may further adversely impact the already tenuous supply of medications. Furthermore, the feverish pace frequently encountered in the operating room is not always conducive to zealous examination of every pharmaceutical vial.

Although not all contaminants are visible upon routine examination, near misses such as this suggest that continued vigilance of pharmaceutical supplies remains necessary with repeated reports of contaminants and interrupted production such as occurred recently with propofol.

Reference

1. Meyer T, Martin E, Prielipp R: The largest health care associated fungal outbreak in the U.S. *APSF Newsletter* 2013; 28:4-7.

Davide Cattano, MD
John Henschel, MD
Ung Betty, Rph
Evan G Pivalizza, MD
Houston, TX

APSF Board of Directors Workshop

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

Saturday, October 24, 2015, 1:00 pm to 3:00 pm Upper Ballroom 20D
San Diego Convention Center, San Diego, CA

Presentation and Subsequent Discussion of APSF Educational Videos with Members of the APSF Board of Directors in Small Breakout Groups:

Operating Room Fires

Perioperative Visual Loss (POVL)

Simulated Informed Consent Scenarios for POVL

Q&A

Medical Air Supply Causes Rapid Inflow of Water Into Flow Meters

Q Dear Q&A,

We were using oxygen and air with sevoflurane for a case in the cystoscopy suite. During the maintenance phase of the case, we found what we assumed to be water inside the air flowmeter, with its float rising and dropping rapidly and the liquid spilling into the next flowmeter (nitrous oxide). We promptly turned off the air flow. We went through a machine inspection and were prepared to take patient off the machine at the first sign of fluid getting into the oxygen flowmeter. We disconnected the air pipeline supply and the connectors were discovered to be wet. We immediately contacted plant operations, and they informed us that there was a failure of the dehumidifier in the medical air pipeline system. We then proceeded to disconnect all of the machines from the air pipeline. There were no alarms for this problem. We disconnected the air supply before any of the other machines could be affected. Fortunately, there were no clinical issues with the patient.

I think there is something to be said about the safety of being able to see your flowmeters—as opposed to the digital interface in the newer anesthesia machines.

As a corollary, fixing the machine will cost about $8,000 and it will be out of service for an unknown period of time. It took a week to fix the pipeline air supply problem. Luckily, no harm came to patients out of this event.

Sincerely,
Alvaro Segura-Vasi, MD
Florence, Alabama

Rapid inflow of water into air and nitrous oxide flow meters caused by water in medical air supply.

Water rushing from medical air supply.

A Dear Dr. Segura-Vasi,

This is a problem that is more common than one might realize. The last letter that we received about this same problem was approximately 5 months ago. When hospitals create their own medical air, there are multiple sources of water that can ultimately end up in the air pipeline supply. First, the use of oil-less compressors that may have water seals (rather than hydrocarbon lubricants) to help maintain purity standards for medical air can introduce water into the medical compressed air. Another source of water is the humidity of the outside ambient air. In Alabama, the humidity is relatively high and the water in the air that is taken into the compressor introduces a great deal of water into the medical air system. That water is typically eliminated by a dryer located within the system. There are also dew point sensors scattered throughout the air pipeline system to electronically monitor the water content of the medical air system to prevent the situation that you described. There are several potential points of failure, but the most common that causes the situation you described is the failure of the dryer. There is a very good review article on Medical Air that can be found in the summer 1996 issue of the *APSF Newsletter*, which can be accessed at http://www.apsf.org/newsletters/html/1996/summer/apsfmedair.html.

Your approach to this problem was exemplary. Turning off the air flowmeter and disconnecting the hose to the air pipeline is imperative to prevent water from entering other flowmeter tubes. The machine you described has the air flowmeter on the left side of the flowmeter bank with nitrous oxide as the second flow tube and oxygen on the far right. You mentioned that water was flowing into the nitrous flow tubes. Some

See "Q&A," Next Page

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

Q&A

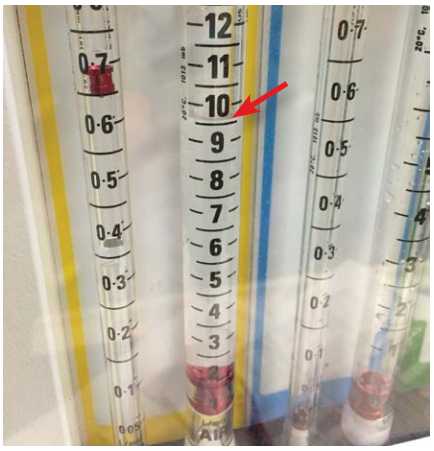
High Humidity May Contribute to Water in Medical Air Supply

"Q&A," From Preceding Page

machines have the air flowmeter in the middle, in which case the water would have entered the oxygen flowmeter. Potential failure of the rotameters due to water or residual debris requires that respiratory gas analysis be used for monitoring gas concentrations. Calling the anesthesia machine manufacturer and asking them to evaluate and repair the anesthesia machine before it can be used again is vital for subsequent safe use of the machine. Machines that were disconnected and thought to be contaminant-free should be checked for proper needle valve and flow tube accuracy before their next use. All anesthesia machines deemed safe for use should use air tanks (E cylinders) until Plant Operations informs you that the pipeline is dry and safe to use, and that the dryers are fully functional and providing the proper dew point.

You also made a very important point when you said, "I think there is something to be said about the safety of being able to see your flowmeters—as opposed to the digital interface in the newer anesthesia machines." Again, the importance of a respiratory gas analyzer cannot be overstated, especially when you don't know what the electronic flow controllers and measuring devices will do under such circumstances.

A. William Paulsen, PhD, AA-C
Chair, APSF Committee on Technology



Water level in fresh gas flow meter for air (red arrow).

More Q&A:

Problems with Automated Anesthesia Machine Checkout

Q Dear Q&A,

We write to describe an instance of anesthesia machine ventilator failure during provision of anesthesia. The case in point was an emergency vascular operation for a pulseless lower extremity. In preparation for the case, the anesthesia machine checkout was performed on the Dräger GS Premium. All tests confirmed that the anesthesia machine was indeed operational and ready for use.

The patient was brought to the operating room, and, after immediate re-evaluation, the patient was induced. After confirmation of bilateral breath sounds and verification of end-tidal CO_2, manual ventilation was discontinued and the mechanical ventilation was initiated. At this point the ventilator immediately alarmed "Ventilator Failure!!!," "Check APL Valve!!!," "Apnea Pressure!!" (Figures 1, 2). Interestingly, there was no loss of tidal volumes at this point, and, contrary to the alarms, the ventilator appeared to function appropriately. Despite stopping mechanical ventilation and commencing manual ventilation, the alarm continued. After several minutes of inspection of the circuit, a small cut in the APL valve tubing was discovered. The tubing was replaced, the alarms ceased, an uneventful anesthetic ensued, and there were no untoward effects on the patient.

In an effort to delineate whether this type of ventilator failure can be discovered by routine automated machine checkout, we initiated mechanical ventilation mode both before and after making a small cut on the APL valve tubing. The machine passed the ventilator leak test, the system leak test, the compliance test, and the safety relief valves test after making the cut on the APL valve (Page 33, Figures 3, 4); yet , the ventilator flashed the same failure alarms as previously mentioned after mechanical ventilation was initiated. (Figures 1, 2).

The purpose of this letter is to remind anesthesia providers that successful automated machine checks, while useful, do not preclude the possibility of machine failures. Indeed, in a previous letter response to the APSF, it was noted by Dräger "No anesthesia system on the market has completely automated all aspects of the checkout procedures and eliminated the need for manual checkout" *(APSF Newsletter,* winter 2009–2010). The case highlighted above underscores this message and anesthesia team members should keep in mind this unique case of anesthesia machine failure.

Matthew Charous, MD
Michael Presta, DO
Scott Byram, MD
Loyola University Medical Center
Maywood, IL

See "Q&A," Next Page

Figure 1. The authors successfully performed the anesthesia machine checkout on the Dräger GS Premium machine prior to anesthesia induction. At the initiation of mechanical ventilation, despite the machine passing checkout, the machine alarms sounded for "Ventilator Failure!!!," "Check APL Valve!!!," "Apnea Pressure!!"

Figure 2. Despite the ventilator alarms, there was no loss of tidal volumes, and the ventilator appeared to function appropriately. The alarms continued—even after resumption of manual ventilation. Close inspection revealed a small cut in the APL valve bypass tubing as the source of the problem.

Q&A

Functional and Automated Tests of Breathing Circuit and Ventilator Required

"Q&A," From Preceding Page

A **Dear Dr. Charous,**

Dr. Charous and colleagues aptly point out that the automated machine checkout procedures do not preclude the possibility of machine failure. Carrying this concept a step further would be to recognize that the more solenoid valves and electronics that have to be added to completely and automatically check every aspect of anesthesia performance, the more there is potential for catastrophic events to occur.

In Charous' reported incident, the anesthesia machine performed exactly as designed. The automated checkout procedure did not find any faults among those machine elements that were part of the automated test algorithm. In spontaneous/manual ventilation mode, the machine performed as expected. However, when the ventilator was switched on, with a leak in the APL bypass hose, the machine quickly alarmed, announcing "ventilator Failure Check APL Valve" indicating a leak in the APL Bypass hose. The machine reverted to spontaneous/manual ventilation mode, enabling the patient to be manually ventilated.

This incident emphasizes the need for an enhanced checkout procedure that includes a functional test of the breathing circuit and ventilator. Before applying the breathing circuit to the patient, the breathing bag should be removed from the bag arm and connected to the circuit elbow or wye piece. The oxygen flush should be used to inflate the breathing bag, which is acting as a lung. The ventilator should be activated and the "lung" observed for inflation and deflation with each breath. The breathing circuit pressure should be checked along with the exhaled volume. Only after a successful test should the breathing bag be returned to the bag arm and the APL valve set to minimum in preparation for the patient. Employing such a test every time the machine is to be used will uncover a number of breathing circuit issues that could interfere with ventilation of the patient.

A. William Paulsen, PhD, AA-C Chair
APSF Committee on Technology

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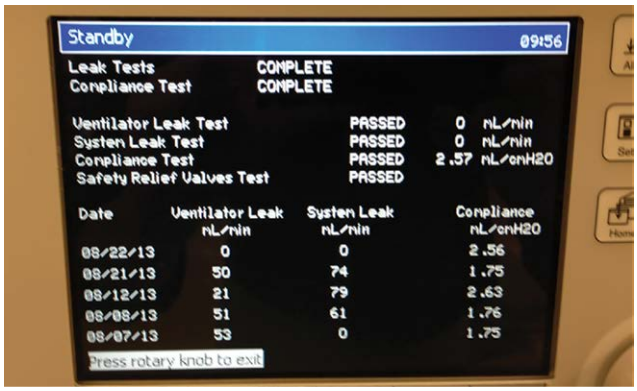

Figure 3. In an effort to replicate this scenario and to delineate whether this type of ventilator failure can be discovered by routine, automated machine checkout, the authors initiated mechanical ventilation mode both before and after making an intentional small cut on the APL valve bypass tubing. The machine passed the ventilator leak test, the system leak test, the compliance test, and the safety relief valves test after the cut in the APL tubing was made, but the venilator alarms sounded once mechanical ventilation was started. (Read Dr. Paulsen's answer to find out how to prevent this scenario from happening to you.)

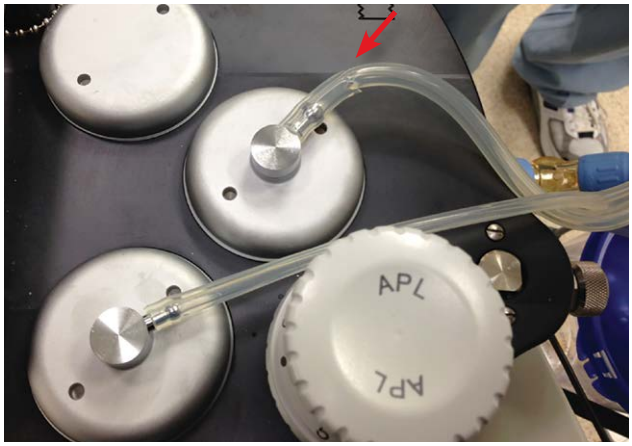

Figure 4. Small cut on the APL valve bypass tubing (red arrow).

Dear SIRS

Manufacturer Responds Regarding Defective Gas Sampling Line

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

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.

Dear SIRS:

We provide anesthesia services for a small outpatient surgery center. During the ASA/FDA recommended pre-anesthetic checkout, 3 anesthesia machines failed the "breathing system pressure leak testing." Standard troubleshooting methods were employed, including replacing anesthesia circuits, replacing water traps, and checking all connections and fittings without resolution. Further troubleshooting identified the failure in the gas sampling line connector. The gas sampling lines were not properly fused with the connector (see Figure 1). This defect was noted on multiple circuits, explaining why replacing the circuit did not correct the leak. The failure was immediately addressed by replacing the gas sampling lines. The quality assurance department of the circuit manufacturer was contacted to initiate corrective actions in the manufacturing process (see below).

CDR Mark J. Lenart MD
LCDR Shane E. Lawson CRNA, MS
Department of Anesthesiology, Naval Medical Center Portsmouth, Portsmouth VA

Reply:

I would like to provide you an update regarding Pall Medical's investigation into sporadic reports of a leak with the Pall Ultipor™ Anesthesia Breathing Circuit System (Adult 72" Circuit) product code VM72COAX. The referenced leaks have been isolated to the gas sampling line where the tubing is bonded to the connector and have been detected during the pre-use ASA/FDA leak testing.

Investigation Findings:

Returned samples were thoroughly tested and the report of a leak was confirmed. A root cause analysis has been conducted and the following potential causes were identified:

1. An insufficient solvent application occurred during the manual tubing to connector assembly process. Insufficient solvent could permit dry spots to occur resulting in the reported leaks.
2. The leak test equipment was found to be functioning properly however; it is believed that the operator failed to identify and reject the defective product.

Actions Implemented

To reduce the potential for recurrence, the manufacturing facility implemented the following actions:

- The bonding process has been improved to include the use of an automatic solvent level control on the solvent dispenser for a more consistent application.
- The solvent bonding instruction was revised to include the rotation of the tubing by >45 degrees for a more consistent application of the solvent on the tubing surface.
- An indicator light, "Pass" (Green Light) "Fail" (Red Light), was implemented on the test equipment as a visual aid for improved leak detection.
- Test equipment was modified to have an audible sound if a leak is present in order to enhance the operator's ability to detect a failed unit.
- Associated work instructions were updated and training sessions held with manufacturing personnel.

Pall Medical continues to monitor the effectiveness of the above actions and will implement additional improvements if deemed necessary.

We appreciate your interest in this matter and hope the information above meets your needs. If you should have any questions or should require additional assistance, please do not hesitate to contact the Pall Medical Customer Care Hotline at 1-800-645-6578.

Sincerely,
Kathleen Zimmermann
Sr. Director Quality Operations
Pall Medical

PALL Medical

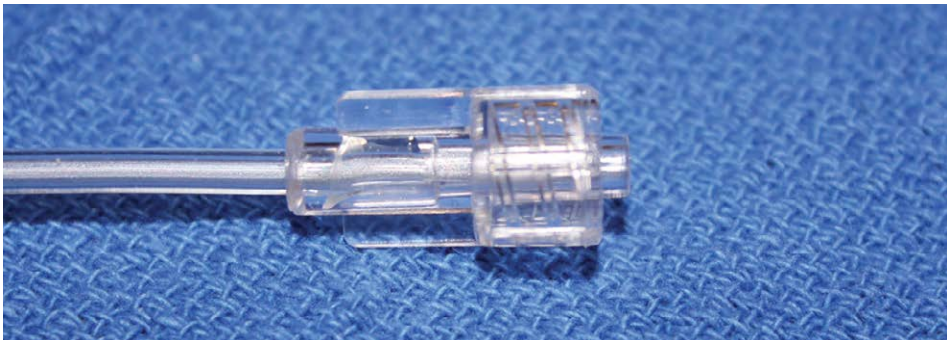

Figure 1. Defective Connector.

Anesthetic Drugs May Interact With Medications Used for Parkinson's Disease

by Lorri A. Lee, MD, and Tricia A. Meyer, PharmD, MS, FASHP

An estimated one million people in the United States have been diagnosed with Parkinson's Disease (PD) making it one of the most common neurological disorders in patients. This number is estimated to double in the next 30 years as PD is associated with increasing age. PD patients have a deficiency of dopamine in their brain and many of their medications are used to increase this neurotransmitter. They are frequently very sensitive to missing even one dose of their Parkinson medications and may exhibit increased rigidity, loss of balance, agitation, and confusion if their dosing schedule is delayed. Neuroleptic malignant syndrome or parkinsonism-hyperpyrexia syndrome can develop if their medications are held too long or as a result of serious infection.[1] Many drugs used in the perioperative period, such as metoclopramide, butyrophenones (haloperidol, droperidol), and phenothiazines (promethazine, prochlorperazine) have anti-dopaminergic activity that can worsen the symptoms of PD.

Depression is a common neuropsychiatric manifestation of PD and many of these patients will be taking serotonergic antidepressants that can interact with serotonergic medications administered in the perioperative period and cause the potentially fatal serotonin syndrome. The potent monamine oxidase inhibitor (MAOI) methylene blue is a frequent precipitator of serotonin toxicity in the hospital in patients who are taking other serotonergic medications. Methylene blue predominantly inhibits MAO-A which is responsible for deaminating serotonin.

PD patients may be prescribed selective MAOI-B medications such as selegiline and rasagiline that inhibit metabolism of dopamine. Though caution is still advised, several studies have demonstrated that the risk of serotonin syndrome with these selective MAOI-B drugs is extremely low, even in combination with serotonergic antidepressants.

Acetylcholinesterase inhibitors for PD dementia (rivastigmine, donepezil, and galantamine) are commonly prescribed, and these drugs have been associated with a prolonged effect of succinylcholine (up to 50 minutes) and increased resistance to non-depolarizing neuromuscular blocking drugs.

Treatment for PD is polypharmacy with the potential for numerous adverse drug interactions with perioperative medications. Anesthesia professionals should be aware of the symptoms and signs of PD exacerbations, neuroleptic malignant syndrome (parkinsonism-hyperpyrexia syndrome), and serotonin toxicity[2] and understand which commonly used anesthetic drugs possess anti-dopaminergic and serotonergic activity.[3] In addition, PD patients have difficulty swallowing and are at increased risk for aspiration and falls. They have increased lengths of stay and increased complications with surgery.[1]

Because of these concerns, the Institute for Safe Medication Practices (ISMP) issued a recent medication safety alert with recommendations on the medication management and perioperative care of PD patients (https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=103).[4] Placing these patients as first start cases and making sure they stay on their scheduled PD medications during their NPO status is recommended when possible. For elective cases, some medications such as acetylcholinesterase inhibitors may be stopped 1–2 weeks prior to surgery but should preferably only be discontinued in consultation with the patient's neurologist. Development of departmental guidelines for perioperative management of PD patients may be useful to detail the myriad potential drug interactions and perioperative care issues.

The authors have no conflicts of interest to declare for this article.

Dr. Lee is Co-Editor of the APSF Newsletter *and Professor of Anesthesiology and Neurological Surgery at Vanderbilt University Medical Center in Nashville, TN.*

Dr. Meyer is Regional Director and Associate Professor of Anesthesiology at Baylor Scott & White Health, Texas A&M College of Medicine in Temple, TX.

References

1. Katus L, Shtilbans A. Perioperative management of patients with Parkinson's disease. *Am J Med* 2014; 127:275-80.
2. Ables AZ, Nagubilli R. Prevention, recognition, and management of serotonin syndrome. *Am Fam Physician* 2010;81:1139-42.
3. Baruah J, Easby J, Kessell G. Effects of acetylcholinesterase inhibitor therapy for Alzheimer's disease on neuromuscular block. *Br J Anaesth* 2008;100:420.
4. Institute for Safe Medication Practices. Delayed administration and contraindicated drugs place hospitalized Parkinson's disease patients at risk. March 12, 2015. https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=103. Accessed August 13, 2015.

Letter to the Editor:
Development of Serotonin Syndrome with 5HT-3 Receptor Antagonist

To the Editor:

I read with interest the June 2015 *APSF Newsletter* article by Dr. Adair Locke regarding the risk of serotonin toxicity. I wanted to alert practitioners to a recent FDA serotonin syndrome warning on a group of medications that are frequently used in the perioperative setting.[1]

The FDA regularly posts important information to help medical professionals in prescribing and monitoring the safety of drug therapy. These alerts are a result of clinical research and/or postmarketing surveillance data. These risks may necessitate changes to the drug's prescribing information, even after the drug has been on the market and widely used. In September 2014, the FDA changed the safety labeling for 5 HT-3 receptor antagonists—ondansetron, granisetron, palonosetron, and dolasetron. These agents are used for the prevention and treatment of postoperative nausea and vomiting. The changes were a result of serotonin syndrome being reported with the use of these drugs.[2] The majority of the reports were associated with the concomitant use of other serotonergic drugs which include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors, mirtazapine, fentanyl, lithium, tramadol, and intravenous methylene blue. Some of the reported cases were fatal.

The new warning suggests advising patients of the possible development of serotonin syndrome with use of the 5HT-3 receptor antagonists and agents used to treat depression and migraines. The 5-HT3 receptor antagonists work by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

Tricia A. Meyer, PharmD, MS, FASHP
Regional Director
Associate Professor of Anesthesiology
Baylor Scott & White Health
Texas A&M College of Medicine
Temple, TX

References

1. US Food and Drug Administration. Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER). Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm418818.htm (Accessed August 3, 2015)
2. Gollapudy, S, Kumar, V, Dhame, M. A case of serotonin syndrome precipitated by fentanyl and ondansetron in a patient receiving paroxetine, duloxetine, and bupropion. [Letter to editor]. *Journal of Clinical Anesthesia* 2012; 24:251-260.

Letter to the Editor:

Fluroescein May be Used for Ureteral Identification

To the Editor:

I read with interest your recent article "Methylene Blue and the Risk of Serotonin Toxicity." There was mention of alternative intraoperative urologic dye markers, although the suggestions involve using near infrared light (indocyanine green) or administering the marker orally (phenazopyridine and vitamin B complex).

In our institution, we have used intravenous fluorescein to visualize the ureteral meatuses and confirm ureteral patency. A dose of 100 mg of fluorescein (AK-Fluor, Akorn Inc, Lake Forest, IL) resulted in a bright yellow ureteral jet a few minutes after injection. This was easily visualized without need for ultraviolet illumination.

Fluorescein has been used to identify ureters in the obstetric literature,[1] with excellent efficacy and minimal side effects. Although rare severe reactions have been reported, most adverse reactions are mild and are associated with larger fluorescein doses.[2]

When considering alternatives to methylene blue, readers may want to include intravenous fluorescein.

Glenn Shopper, MD
Albert Einstein Health Network
Philadelphia, PA

References

1. Doyle PJ, Lipetskaia L, Duecy E, et al. Sodium fluorescein use during intraoperative cystoscopy. *Obstet Gynecol* 2015;125:548-50.
2. Kwiterovich KA, Maguire MG, Murphy RP, et al. Frequency of adverse systemic reactions after fluorescein angiography. Results of a prospective study. *Ophthalmology* 1991;98:1139-42.

Letter to the Editor:

An Alternative Succinct Checklist Offered for PACU Handoff Communication

To the Editor:

We wish to thank the authors and editors of the APSF for publishing the study, "Improving Post Anesthesia Care Unit Handoff by Implementing a Succinct Checklist,"[1] in the 2015 summer issue of the *APSF Newsletter*. This article informs the anesthesiology community about the importance of effective communication throughout a patient's perioperative journey.

At MD Anderson Cancer Center, we have implemented and continue to modify our own postoperative handoff protocol, which has been presented at the 2015 ASA Practice Management Conference and the IARS (International Anesthesia Research Society, 2015). We would like to share some of our experiences in order to complement the work performed by Potestio and colleagues and perhaps further guide other groups who are about to embark on similar projects.

In this study, the authors customized their checklist by selecting from items identified in the handoff literature as being important for postoperative handoffs and they organized the items into Patient, Procedure, and Medications for their handoff report.[1] While succinct and organized, there are 2 disadvantages with this method. First, even with a short list, not all items will be relevant to every handoff and other items may be missed. Potestio et al. acknowledge this drawback by stating that "any standardization tool is often going to be too comprehensive or too efficient."[1] Second, providers giving the handoff reports are forced to follow the order of the checklist. While this may be beneficial for less experienced providers who are just learning how to perform handoffs (such as junior residents who made up the majority of study subjects in this study), following a rigid checklist may elicit resistance among more experienced clinicians because it interferes with the "flow" of their practiced, yet not necessarily complete,[2] handoff reports.[3]

In order to address these 2 issues, our protocol first allows anesthesia providers to give a verbal report in the manner of their choice. In contrast to pre-flight aviation checklists and surgical "time out" checklists, where a number of mostly unrelated items are sequentially addressed, unstructured anesthesia handoff reports are often told as a "story."[3] For example, a "non-standardized" report might state: "Mrs. X has a history of PONV so I administered ondansetron prophylactically" while in many "standardized" checklists, PONV and anti-emetics would be mentioned in separate sections (e.g., Patient and Medications). This liberal approach also allows providers to have the freedom to focus on the important details pertinent to the individual clinical scenario.

We do, however, still include a standardized checklist as part of our handoff protocol. After delivering their customized handoff report, anesthesia providers are asked to review a "Read and Verify" checklist (as opposed to the more common "Read and Follow" type checklists such as the one described in the authors' study). This checklist contains 10 items that the handoff improvement team, which included anesthesiologists and PACU nurses, felt were critical to consider in every handoff exchange. It includes routine topics such as allergies and difficult airway, items required for CMS reimbursement such as hemodynamic stability,[4] and less frequently encountered items such as communication barriers (language, hearing impairment) which can be overlooked as providers perform their "routine" handoff.

See "PACU Checklist," Next Page

PACU HANDOFF CHECKLISTS

SURGERY CHECKLIST:
☐ PRIMARY SERVICE
☐ CONTACT PERSON/PAGER NUMBER
☐ PROCEDURE AND INCISION SITES (dressings, drains, tubes)
☐ SIGNIFICANT SURGICAL EVENTS
☐ POST OP CARE (if applicable)
o BP Target:
o Flap:
o Positioning:
o Other:
☐ LABS/IMAGING: CT/MRI/CXR
☐ DISPOSITION: INPT/OUTPT/TRANS PACU/EXT RECOVERY
☐ ORDERS ENTERED? PRESCRIPTION VERIFIED? MEDICATION RECONCILIATION?
☐ PRIMARY POST OP CONCERN
☐ QUESTIONS?

ANESTHESIA CHECKLIST:
☐ SIGNIFICANT SURGICAL/MEDICAL HISTORY
☐ DRUG ALLERGIES
☐ PACEMAKER/ICD? If Yes, needs interrogation?
☐ RESISTANCE/SENSITIVITY TO ANESTHETICS/SEDATION?
☐ DIFFICULT AIRWAY?
☐ OXYGENATION ISSUES?
☐ HEMODYNAMIC EVENTS/STABILITY
☐ OTHER INTRAOP EVENTS
☐ SPECIAL ANALGESIA (ERAS premeds, Exparel, Nerve blocks)
☐ SPECIAL PATIENT CONCERNS (PONV, Chronic Pain, Communicable Disease, Language, Disability, Psychosocial)
☐ PRIMARY POST OP CONCERN
☐ ANESTHESIA CONTACTS: Anesthesiologist/CRNA
☐ QUESTIONS?

Handoff Report Can Be Customized

"PACU Checklist," From Preceding Page

To summarize, our handoff report can be adjusted to the simplicity/complexity of the patient/procedure because anesthesia providers are using their own judgment to decide how much detail is needed while key safety items are still reviewed as clinicians "skim" through the checklist. The resulting customized protocol was our attempt to strike a balance between individualization and standardization.

Two further points are worth noting. First, while checklists address the content of handoff protocols, it is also important to address process. For example, our protocol states that verbal handoff should occur only after the patient's monitors have been attached, a baseline set of vital signs have been taken, and the patient is stable. This avoids multitasking[5] and allows the PACU nurses to give providers their full attention when the time comes to take report. We also found that having the PACU RNs complete a worksheet based on the checklists helped them to focus on the transmitted information.

Second, we encourage the authors to follow up with their statement to implement handoff reports, including a checklist, from their surgery colleagues to guide in the patient's immediate postoperative care. In our case, our initial assessment of existing handoffs and feedback from PACU RNs suggested that input regarding surgical issues such as incision sites, drains, patient disposition etc., were considered important to address as part of a complete postoperative handoff discussion. Therefore, a surgical checklist and verbal report by a surgical representative became part of our handoff protocol from inception. We found that surgical leadership support, presentation of local data regarding unsatisfactory handoffs, and examples of postoperative handoff research from their own surgical literature[6] all helped to improve compliance. Perhaps these suggestions will be useful to Potestio and his colleagues as they move to build upon their current protocol.

Thank you again for sharing your work in this important area.

Drs. Jens Tan, Shreyas Bhavsar, Katherine Hagan, and Javier Lasala are Assistant Professors in the Department of Anesthesiology and Perioperative Medicine at the University of Texas MD Anderson Cancer Center in Houston, TX.

References

1. Potestio C, Mottla J, Kelley E, et al. Improving post anesthesia care unit (PACU) handoff by implementing a succinct checklist. *APSF Newsletter* 2015; 30(1):13-15.
2. Ilan R, LeBaron CD, Christianson MK, et al. Handover patterns: An observational study of critical care physicians. *B\MC Health Serv Res* 2012;10:11
3. Patterson ES. Structuring flexibility: The potential good, bad and ugly in standardization of handovers. *Qual Saf Health Care* 2008;17:4-5.
4. Anesthesia Quality Institute. 2015 PQRS QCDR Measures by NQS Domain. Available at: http://www.aqihq.org/files/pqrs/2015_PQRS_QCDR_MEASURES_BY_NQS_DOMAIN.pdf. Accessed August 11, 2015.
5. van Rensen EL, Groen ES, Numan SC, et al. Multitasking during patient handover in the recovery room. *Anesth Analg* 2012;115:1183-7.
6. Nagpal K, Abboudi M, Manchanda C, et al. Improving postoperative handover: a prospective observational study. *Am J Surg* 2013;4:494-501.

Vision

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

&

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.

POC Glucose Meters Less Accurate in Critically Ill Patients

"POC Meters," From Page 20

Recent Regulatory Issues

The regulation of POC meters for hospital use is currently undergoing significant debate. In 2006, the Food and Drug Administration (FDA) issued accuracy guidelines, which called for 95% of device readings above 75 mg/dL to be within 20% of reference values and within 15 mg/dL for reference readings <75 mg/dL. Along with this guidance, the FDA document stated: "Clarify that critically ill patients (e.g., those with severe hypotension or shock, hyperglycemic-hyperosmolar state, hypoxia, severe dehydration, diabetic ketoacidosis) should not be tested with blood glucose meters because inaccurate results may occur."[9] Although the vast majority of the marketed meters didn't meet even the 2006 standards, the FDA issued draft guidance in 2014 tightening the standards such that 99% of the readings >70 mg/dL needed to be within 10% and those <70 mg/dL had to be within 7 mg/dL.

Following this recent FDA draft guidance, the Centers for Medicare & Medicaid Services (CMS) issued a 2014 document, stating that if meters were not cleared for use with critically ill patients (none at the time were), they could not be used for these patients. Interestingly, "critically ill" was not defined.

After this CMS statement, hospital laboratory directors were left with a major problem. Since the vast majority of hospital glucose tests were done with POC meters, what should they do? In addition, critically ill was not defined, so which patients did this guidance apply to?

In May of 2014, a number of clinicians (including the first author) met with representatives from FDA and CMS to initiate dialogue concerning the stance of CMS that POC meters could not be used with critically ill patients.[9] The discussion centered around several issues including possible alternatives, defining critically ill, and asking for a moratorium on the elimination of the meters from the hospital environment. The author presented his view that there is currently no realistic alternative to using meters in many ICUs and operating rooms. CLD measurements, although very accurate, can take up to an hour for results to be obtained. Other POC glucose measurement technologies (iSTAT® and HemoCue®) are more time-consuming, expensive, and are not available in many units. Finally, blood gas measurements do not have widely-known accuracy profiles and are not available in many operating rooms and ICUs.[9]

In March of 2015, following input from many stakeholders, CMS temporarily suspended its call for elimination of the meters from use with the critically ill. However, it is not known when this "moratorium" will be revisited.

Recommendations for anesthesia care providers Inoue and colleagues published a literature search analyzing 21 studies of POC glucose measurement devices in critically ill adults. Their conclusion was: "Because blood-glucose monitoring was less accurate within or near the hypoglycemic range, especially in patients with unstable hemodynamics or receiving insulin infusion, we should be aware that current blood glucose-monitoring technology has not reached a high enough degree of accuracy and reliability to lead to appropriate glucose control in critically ill patients."[7]

Your laboratory director is a great resource for information regarding particular meter profiles and regulatory trends. For more information on overall meter accuracy and interferences, see Rice et al.[5] For recent information regarding POC glucose meter regulatory issues, see Klonoff et al.[9]

Disclosure: Dr. Rice serves on the Roche Diabetes Advisory Boards.

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References

1. Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab* 2002;87:978-82.
2. Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001;345:1359-67.
3. Finfer S, Chittock DR, Su SY, et al. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med* 2009;360:1283-97.
4. Jacobi J, Bircher N, Krinsley J, et al. Guidelines for the use of an insulin infusion for the management of hyperglycemia in critically ill patients. *Crit Care Med* 2012;40:3251-76.
5. Rice Mj, Pitkin AD, Coursin DB. Glucose measurement in the operating room: More complicated than it seems. *Anesth Analg* 2010;110:1056-65.
6. Le HT, Harris NS, Estilong AJ, Olson A, Rice MJ. *JDST* 2013;7(2):489-99
7. Inoue S, Egi M, Kotani J, et al. Accuracy of blood-glucose measurements using glucose meters and arterial blood gas analyzers in critically-ill adult patients: systematic review. *Crit Care* 2013;17:R48.
8. Disque A, Dhillon A, Gritsch A. Icodextrin causing glucose meter error and severe hypoglycemia after deceased donor renal transplant in a patient receiving continuous ambulatory peritoneal dialysis. *Anesth Analg Case Reports* 2013;1:89-91.
9. Klonoff DC, Vigersky RA, Nichols JH, et al. Timely hospital glucose measurement: Here today, gone tomorrow? *Mayo Clinic Proc* 2014;89:1331-5.

Dangers Exist for Patients and Anesthesia Professionals in Extreme Remote Locations

"Extreme Locations," From Page 26

therapy requires daily treatments for a period of 3–4 weeks.

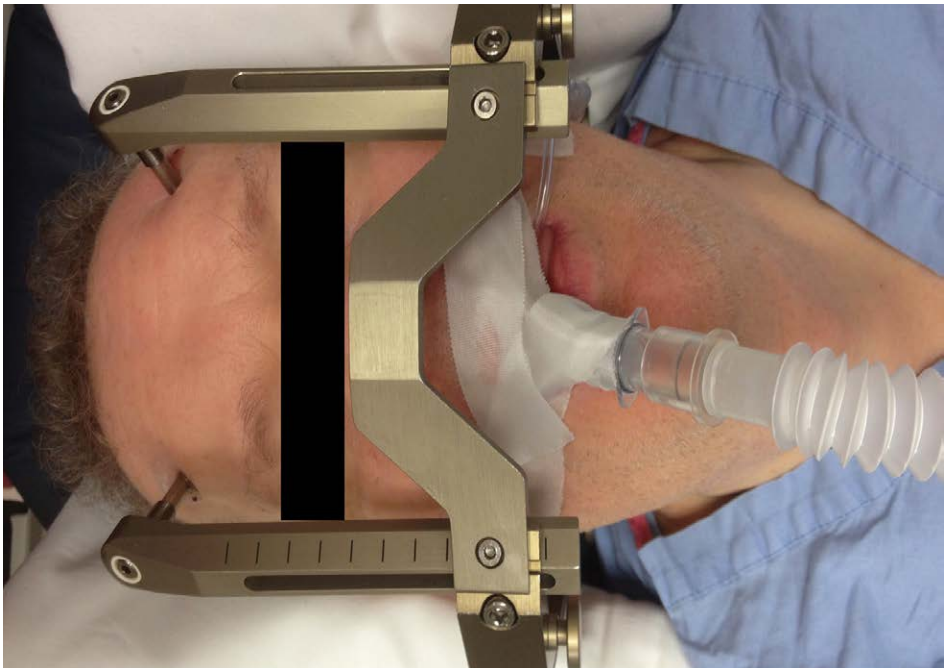
For treatment, a patient lies on a table called a couch. This couch projects into a 2-story, 190-ton rotating gantry that contains a proton nozzle. To create a proton beam, the nozzle is the focal point for a high-energy synchrotron generating 250 million electron volts. In a true emergency, this equipment poses an added risk to the safety of the patient because accessibility is limited. The treatment area is considered a nuclear containment area. The construction of the containment area consists of a reinforced concrete wall, 8-feet thick. This degree of containment does not allow for any person other than the patient to be inside the treatment room.

After induction of anesthesia, a scout positioning X-ray is performed to properly align the beam. During this X-ray, standard shielding precautions are employed. Once the nozzle is aligned, the proton treatment begins. Direction of the protons to the target area is accomplished by channeling through an individualized brass aperture. Due to the creation of various radioactive species within the brass, the handling of these plates should be minimal until 15 minutes after proton treatment. After a period of 1 week, the radioactivity of the brass apertures becomes insignificant.[1]

During treatment, the anesthesia providers monitor the patient from a control room equipped with audio and video monitors. The major limitation of anesthesia care during proton therapy is the degree of separation required between patients and providers. The beam can be shut off instantly and the atmosphere is safe at that point. The response time is about 30 seconds from control room to patient. The time to remove a positioning mask is about 10 seconds.

Continuous propofol infusion is our anesthetic of choice. Since there is no pain associated with the procedure, we attempt to maintain spontaneous breathing of the patients. Induction is usually performed with parental presence and with the assistance of a child life therapist. If old enough, we usually distract the patient by having them play a game on an iPad. After adequate anesthesia depth is achieved, the patient is positioned on the couch and either a custom cradle or mask is applied. Since the gantry rotates around the patient, IV line and monitor cables must be of sufficient length to extend to the patient. The patient remains at a static location and the gantry drum moves around the patient during alignment, but the gantry is static during treatment. We did configure a small screen to mirror the anesthesia monitor to allow us to visualize the monitor during positioning.

All personnel working at the proton center receive annual emergency procedure training specific to the proton center. The training focuses on evacuation plans and hazards relevant to the proton center. Anesthesia providers are also monitored with special radiation dosimeter badges that also measure neutron exposure.

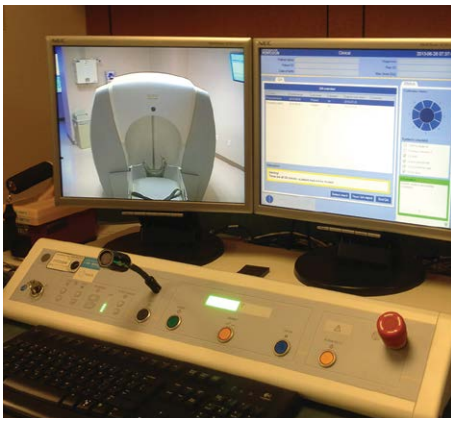


Gamma knife patient positioned within a fixed frame with an LMA in place. Availability of an appropriate Allen wrench allows emergency removal of cross bar.

Although not published in literature, or reported by manufacturers, the functional longevity of computers, vital signs monitors, and displays seem to be reduced considerably for such devices, which are used in the containment area during treatment.

PET Scanning

Occasionally, the anesthesia team may be approached to provide care for patients undergoing positive electron tomography (PET) scanning. Generally speaking, the radiation physics behind PET scanning differs greatly from other imaging modalities. In a PET scan, the patient receives a radioactive isotope, fluorodeoxyglucose (FDG), and is placed under a camera. The scan is carried out in a similar fashion to other nuclear medicine scans performed by scintigraphy. However, the key difference is that the isotope used results in the patient becoming a high dose radioactive source. In dealing with these patients, they are constantly emitting a high dose of radiation. Common shielding such as leaded aprons are not effective in neutron radiation and actually may expose the wearer to higher doses of radiation due to the entrapment of radioactive particles underneath the apron. Due to the need of patient contact during the application of monitors, induction, and airway intervention in addition to any patient rescue that might be needed, we do not provide anesthetic care for patients undergoing PET scans.



Gamma Knife Station.

Gamma Knife

Gamma knife facilities are becoming more commonplace, even in community hospitals. Claustrophobic patients or patients who cannot lie still for a few hours must be anesthetized for gamma knife treatments. The gamma knife apparatus is a device in which the patient's head is placed in a radioactive cave. The source of radiation is usually cobalt 60. Devices using natural radioactive sources differ from those utilizing generated ionized radiation. The gamma knife is loaded with the cobalt, which continuously emits gamma radiation and decays over time. The radioactive cave is lined with 201 small apertures containing cobalt 60. Combinations of apertures are opened to focus on the brain tumor from different axis points. The treatment length is variable depending on the size and location of the tumor. The anesthesia provider should also inquire of the age of the cobalt.

See "Extreme Locations," Next Page

Airway Access is Limited With Gamma Knife Frame

"Extreme Locations," From Preceding Page

Since the cobalt is under continual decay, when the cobalt is new, treatments might take 1 hour, but as the cobalt ages, less radiation is emitted and the treatment will require up to 4 hours.

The treatment requires the patient's head to be secured in a stereotactic frame. The frame is placed using local anesthesia at the pin sites. Patients are then scanned in an MRI, so if the patient is claustrophobic, anesthesia is induced in the customary fashion. A critical and special consideration is that the frame contains a cross member support which can be re-oriented to facilitate access to the patient's airway. Placement of a supraglottic device is easy to achieve; however, mask ventilation would be difficult due to the location of the frame. For this reason, an appropriately sized Allen wrench should accompany the patient to remove the cross member altogether. In true emergencies, the entire frame can be removed by thumbscrews, but should be a last resort as rescanning must be performed after removal of the frame from the patient. Following the MRI, a series of programming calculations must be made to program the gamma knife. These calculations can take up to an hour to perform, so a delay from end of the MRI scan until beginning of the gamma knife treatment should be planned. Also the location of the gamma knife may not be near the MRI facility so transportation of patients needs to be appropriately planned.

Summary

In all of these locations, it is vital that the anesthesia team be involved in the facility planning. Considerations for medical gas and waste anesthetic gas plumbing must be made during the initial construction design, as retrofitting plumbing through structures such as 8-foot thick walls is impossible.

We have learned many lessons including the need for facilities to plan for alternative patient positioning with respect to electrical and medical gas plumbing and overall operational space. We began with patients in the iMRI only in a neutral supine position with a headfirst orientation, but have since positioned patients prone, lateral, right side awake, and even feet first for soft tissue scanning.

With a proton center, the building must be a free-standing, newly built facility. Anesthesia providers will feel isolated as none of the comforts of the operating room are anywhere nearby. Plans for medical emergencies must be created prior to opening of the facility. Considerations likely will need to include ambulance transportation and transfer arrangements in the event of emergencies. Pharmacy support should be incorporated as the anesthesia care team and the recovery area personnel likely will be the only health care professionals administering medications within the facility.

Anesthesia providers should interface with engineers and vendors to understand how specific systems work and appreciate the hazards specific to these unique environments. Education, planning, and rehearsal of "dry runs" should be carried out to identify issues prior to performing the case. Anesthesia providers should also discuss upcoming technologies with the surgeon prior to performing the case to reduce unanticipated needs such as repositioning or the need for extensions for the circuit or IV/infusion tubing. As with all anesthesia care, success hinges upon communication among surgical team members. The anesthesia provider should also plan with technologists and technicians for particular precautions for the case. A number of photographs have been provided to illustrate the complexities of these complex and cutting edge technologies.

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Reference

1. Mukherjee B. Radiation safety issues relevant to proton therapy and radioisotope production medical cyclotrons. *Radiat Prot Environ* 2012;35:126-134.

Letter to the Editor:

Vial Stoppers: The Hidden Latex Risk in the Perioperative Environment

To the Editor:

Latex is a known cause of allergy and anaphylaxis in the perioperative period. The most common source of exposure has historically been gloves; however, other medical devices also contain natural latex rubber. The FDA required that medical devices containing latex be appropriately and uniformly labeled in 1997; however, vial closures were not included in these regulations. Awareness of latex risk is high, and operating room staffs routinely have protocols in place to minimize exposures in patients at increased risk of allergy or anaphylaxis. Over the past 20 years, in fact, most of our operating theaters have become generally "latex free," with traditional non-sterile latex gloves being replaced with nitrile or vinyl, and latex containing anesthesia equipment (breathing circuit bags, blood pressure cuff tubing, tourniquets) being replaced with non-latex alternatives.

One source of latex, however, still exists in the perioperative environment: rubber vial stoppers. Literature has demonstrated that piercing of a rubber stopper results in measurable quantities of latex in the vial as well as measurable latex antigens in blood after injection. This risk is highest when a vial stopper is punctured multiple times, so some (including the American Society of Anesthesiologists and the American Association of Nurse Anesthetists) have recommended avoiding multi-dose vials for this specific reason, and recommendations have previously been made to the FDA to prohibit the use of these stoppers, without success. Clinical practice continues to vary, however, and despite calls for avoidance of multi-dose vials (for a multitude of reasons), many providers routinely still use single-dose vials for multiple patients (e.g., drawing two 5 mL syringes of succinylcholine from a single 10 mL bottle).

Although some vial stoppers are made with plastics or synthetic rubbers, there is no mandatory labeling for these vials and no simple way of determining if the vial stoppers are plastic or rubber. With the widespread availability of inexpensive non-rubber alternatives and the small but real risk of latex exposure and resultant harm, we suggest that the time has come to regulate the content of vial stoppers in the perioperative environment. We therefore recommend appropriate uniform labeling of medication vial stoppers, identification of rubber vial stoppers, or making plastic stoppers mandatory.

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References

1. Holzman R. Taskforce on Latex Sensitivity. Natural rubber latex allergy: Considerations for anesthesiologists. *ASA Publications*. 2005
2. Proposal to prohibit the use of natural rubber latex for use in elastomeric closures for injection. *Pharmacopeial Forum*. 1996; 22:2886-7
3. Primeau M, Adkinson F, Hamilton R. Natural rubber pharmaceutical vial closures release latex allergens that produce skin reactions. *J Allergy Clin Immunol*. 2001;107:959-62.
4. Heitz J, Bader S. An evidence-based approach to medication preparation for the surgical patient at risk for latex allergy: Is it time to stop being stopper poppers? *J Clin Anesth* 2010;22:477-83.

Team Training for OB Emergencies Improves Response

"OB Emergency Transport," From Page 24

maintained for 1 hour[19] appear adequate to prevent clinically significant hemorrhage.[20,21] Although small bolus doses of oxytocin (3 units administered every 3 minutes up to a total of 3 doses) appear to require less total drug to establish acceptable uterine tone when compared with oxytocin infusions,[22] hypotension with myocardial ischemia may increase with this approach.[18]

For women undergoing unplanned cesarean delivery with risk factors for uterine atony, a brief period (1–5 minutes) of rapid controlled infusion (500 to 1000 milliunits per minute) could be used to establish uterine tone,[17,23] followed by a reduced and more hemodynamically stable maintenance infusion. Following an initial dose of 5 units of oxytocin, the addition of a maintenance infusion (40 units over 4 hours) has been shown to reduce the requirement for secondary uterotonics, but did not have any measurable impact on the incidence of major postpartum hemorrhage.[24]

Team Training to Promote Medication Safety

Evidence supports the use of simulation to improve team performance during emergency situations on labor and delivery.[25] Not only should clinical scenarios be practiced, but attention should also be paid to logistical issues regarding medication administration. During simulations of emergency cesarean, providers should practice preparing blood tubing, and disconnecting, capping, and reconnecting IV and epidural infusions as part of the process of moving the patient and infusion pumps to the operating room. Evaluation and maintenance of IV access should also be emphasized. Drills should be done with simulated patients on magnesium and/or oxytocin infusions so providers are familiar with safe handling of these high risk medications during times of high stress. Outside of simulations, teams can be trained to discuss medication issues either in a pre-operative huddle or during the operative time-out. Obstetricians and anesthesia providers should communicate which infusions will be stopped and which should be restarted and continued throughout the cesarean delivery.

While there are many potential hazards (Table 3) associated with medication administration on labor and delivery, the SOAP Patient Safety Committee has also identified several strategies and specific practices to mitigate these hazards. Vigilance, careful systems design, and a culture of robust communication between anesthesia, obstetric and nursing providers can help ensure safe care of parturients regardless of the medications they require during their time on labor and delivery.

The suggested practices presented in this article reflect the opinions and clinical experience of individual members of the SOAP Patient Safety Committee, and have not received official endorsement by SOAP or any another organization.

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References

1. Medication errors in labor and delivery: Reducing maternal and fetal harm. Pennsylvania Patient Safety Advisory 2009;6(Suppl 1):1-6. Available at: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/dec16_6(suppl1)/Pages/01.aspx. Accessed August 11, 2015.
2. Kacmar RM, Mhyre JM, Scavone BM, et al. The use of postpartum hemorrhage protocols in United States academic obstetric anesthesia units. *Anesth Analg* 2014;119:906-10.
3. American Society of Health-System Pharmacists. ASHP guidelines on compounding sterile preparations. *Am J Health-Syst Pharm*. 2014;71:145–66.
4. Task Force on Hypertension in Pregnancy. *Hypertension in Pregnancy.* American College of Obstetricians and Gynecologists. 2013.
5. Conde-Agudelo A, Romero R. Antenatal magnesium sulfate for the prevention of cerebral palsy in preterm infants less than 34 weeks' gestation: A systematic review and metaanalysis. *Am J Obstet Gynecol* 2009;200:595-609.
6. Doyle LW, Crowther CA, Middleton P, et al. Magnesium sulphate for women at risk of preterm birth for neuroprotection of the fetus. *Cochrane Database Syst* Rev 2009;(1):CD004661.
7. Lu JF, Nightingale CH. Magnesium sulfate in eclampsia and pre-eclampsia: pharmacokinetic principles. *Clin Pharmacokinet* 2000;38:305-314.
8. Simpson KR, Knox GE. Obstetrical accidents involving intravenous magnesium sulfate: Recommendations to promote patient safety. *MCN Am J Matern Child Nurs* 2004;29:161-9.
9. Morisaki H, Yamamoto S, Morita Y, et al. Hypermagnesemia-induced cardiopulmonary arrest before induction of anesthesia for emergency cesarean section. *J Clin Anesth* 2000;12:224-6.
10. Bain ES, Middleton PF, Crowther CA. Maternal adverse effects of different antenatal magnesium sulphate regimens for improving maternal and infant outcomes: A systematic review. *BMC Pregnancy Childbirth*. 2013;13:195.
11. Taber EB, Tan L, Chao CR, et al. Pharmacokinetics of ionized versus total magnesium in subjects with preterm labor and preeclampsia. *Am Journal Obstet Gynecol* 2002;186:1017-21.
12. Crowther CA, Hiller JE, Doyle LW, et al. Effect of magnesium sulfate given for neuroprotection before preterm birth: A randomized controlled trial. *JAMA* 2003;290:2669-76.
13. Rouse DJ, Hirtz DG, Thom E, et al. A randomized, controlled trial of magnesium sulfate for the prevention of cerebral palsy. *New Engl J Med* 2008;359:895-905.
14. Reeves SA, Gibbs RS, Clark SL. Magnesium for fetal neuroprotection. *Am J Obstet Gynecol* 2011;204:202.e201-e204.
15. Clark SL, Simpson KR, Knox GE, et al. Oxytocin: New perspectives on an old drug. *Am J Obstet Gynecol* 2009;200:35.e1-6.
16. Simpson KR, Knox GE. Oxytocin as a high-alert medication: Implications for perinatal patient safety. *MCN Am J Matern Child Nurs* 2009;34:8-15.
17. Thomas JS, Koh SH, Cooper GM. Haemodynamic effects of oxytocin given as i.v. bolus or infusion on women undergoing Caesarean section. *Br J Anaesth* 2007;98:116-9.
18. Bhattacharya S, Ghosh S, Ray D, et al. Oxytocin administration during cesarean delivery: Randomized controlled trial to compare intravenous bolus with intravenous infusion regimen. *J Anaesthesiol Clin Pharmacol* 2013;29:32-5.
19. George RB, McKeen D, Chaplin AC, et al. Up-down determination of the ED(90) of oxytocin infusions for the prevention of postpartum uterine atony in parturients undergoing Cesarean delivery. *Can J Anaesth* 2010;57:578-82.
20. Dagraca J, Malladi V, Nunes K, et al. Outcomes after institution of a new oxytocin infusion protocol during the third stage of labor and immediate postpartum period. *Int J Obstet Anesth* 2013;22:194-9.
21. Lee AI, Wong CA, Healy L, et al. Impact of a third stage of labor oxytocin protocol on cesarean delivery outcomes. *Int J Obstet Anesth* 2014;23:18-22.
22. Kovacheva VP, Soens MA, Tsen LC. A randomized, double-blinded trial of a "Rule of Threes" algorithm versus continuous infusion of oxytocin during elective cesarean delivery. *Anesthesiology* 2015; In Press.
23. Lavoie A, McCarthy RJ, Wong CA. The ED90 of prophylactic oxytocin infusion after delivery of the placenta during cesarean delivery in laboring compared with nonlaboring women: An up-down sequential allocation dose-response study. *Anesth Analg* 2015;121:159-64.
24. Sheehan SR, Montgomery AA, Carey M, et al. Oxytocin bolus versus oxytocin bolus and infusion for control of blood loss at elective caesarean section: Double blind, placebo controlled, randomised trial. *BMJ* 2011;343:d4661.
25. Lipman SS, Carvalho B, Cohen SE, et al. Response times for emergency cesarean delivery: Use of simulation drills to assess and improve obstetric team performance. *J Perinatol* 2013;33:259-63.

See "OB Emergency Transport," Next Page

Strategies Suggested to Reduce Medication and Infusion Hazards

"OB Emergency Transport," From Preceding Page

Table 3: Potential hazards associated with medication and infusion management on labor and delivery, and suggested strategies to mitigate each hazard.

Category	Potential Hazard	Suggested Practices to Mitigate Each Hazard*
Venous access	Inappropriate access (e.g., small gauge or absent PIV)	Establish minimum IV access for all parturients (e.g., 18G or larger)
	Venous access infiltration or inadvertent PIV removal during patient transport	Nursing order sets should include the task to verify function of IV with vital sign checks during labor
IV and epidural tubing	Medication infusion lines used in error to administer a desired crystalloid bolus	Clearly label tubing for high-risk medications (oxytocin, magnesium, insulin, epidural solutions), and/or use dedicated color-coded tubing
	No blood tubing available; Kinked or broken tubing; No injection ports (only infusion pump tubing)	Maintain blood tubing in labor rooms and prepared blood tubing in labor and delivery OR(s), keeping in compliance with USP-797. Select tubing systems that do not require replacement upon transfer to the OR.
Infusion pumps	Misprogrammed pump (wrong drug, wrong concentration); Failure to start or stop medication infusion	Utilize safe pumps with preprogrammed medication libraries; utilize standard infusion pumps and tubing in both the L&D unit and all anesthetizing locations in the institution
	Pump errors preventing drug administration (e.g., "Air in line"); Error alarms that distract providers from other tasks	Deploy infusion pump training and competency assessment that includes troubleshooting, strategies to minimize air entrainment, and alarm management; maintain fleet of infusion pumps in optimal working order and budget for timely repair
Magnesium	Uncontrolled bolus administration	Discontinue magnesium prior to proceeding to OR for emergency surgery
	Failure to continue magnesium during cesarean for preeclampsia with severe features, increasing risk for postpartum eclampsia	Restart magnesium infusion for patients with preeclampsia with severe features; verify infusion pump programming with labor and delivery nurse familiar with the obstetric magnesium infusion protocol. It is not necessary to restart magnesium in OR when being used for fetal neuroprotection and delivery is imminent.
Oxytocin	Inappropriate bolus administration prior to delivery	Discontinue oxytocin prior to proceeding to OR; wait to reconnect the infusion to the IV until after delivery of the infant
	Postpartum overdose resulting in hypotension and myocardial ischemia	Consider controlled postpartum infusion via infusion pump or "Rule of Three" administration to promote postpartum uterine tone; monitor for hypotension and myocardial ischemia
Epidural solutions	Medication administered by wrong route (i.e., epidural medication given intravenously)	Consider non-luer lock epidural caps to prevent inadvertent administration of IV medication; use color-coded unique tubing for epidural solutions to discourage wrong route administration
	Dislodgment of the epidural catheter during transport to the OR; entanglement of monitor cables, intravenous lines, and epidural lines that delay transport	Discontinue and cap the epidural infusion and epidural catheter prior to transfer to the OR for emergency surgery; maintain appropriate caps at bedside in each labor room.
Insulin	Uncontrolled infusions of insulin; line entanglement that delays transport or risks PIV dislodgment	Discontinue insulin infusions prior to proceeding to OR for emergency surgery
Antibiotics	Failure to administer antibiotics prior to skin incision for cesarean	Maintain most common antibiotic (e.g., cefazolin) in OR for timely administration
	Administration of medication to patient with stated allergy	Verify allergies prior to administration of antibiotics

PIV: peripheral intravenous cannula; IV: intravenous; OR: Operating room
*Additional suggested practices are included in the Emergency Cesarean Transport Procedure (Table 2 on page 24)

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APSF NEWSLETTER October 2015

Leading the Anesthesia Patient Safety Foundation (APSF) Into the Future

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- Demonstrated evidence of effective leadership in Anesthesiology, at both local and national levels.
- Organizational management experience including daily administration, planning, financial oversight, and fundraising.
- The ability to engage individuals and groups in an inclusive and multidisciplinary approach to improving anesthesia patient safety.
- Membership in the American Society of Anesthesiologists and Board Certification in Anesthesiology.

Interested candidates should send the following documents to Robert A, Caplan, MD (caplan@apsf.org) no later than 9:00 am (PST), Friday, January 8, 2016.

1. A *cover letter* and *personal statement* (not to exceed 1000 words), addressed to Robert A. Caplan, MD, Chair, APSF Search Committee, indicating the applicant's interest and describing the applicant's qualifications for being President.
2. A current *curriculum vitae*.

Please visit the APSF website (www.apsf.org/president) for complete details regarding the responsibilities of the APSF President and the process for selecting this individual.

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