

Postoperative Monitoring—The Dartmouth Experience

By Andreas H. Taenzer and George T. Blike

for the Dartmouth Patient Surveillance Group, with contributions by Susan McGrath, PhD, Joshua Pyke, BE, Michael Herrick, MD, Christian Renaud, MD, and Jessica Morgan, MD, MBA

Hospital inpatients represent a large constituency in the health care system—the National Center for Health Statistics estimated a total of 34.7 million discharges in 2005.¹ Accordingly, much effort has historically been expended to keep these patients safe during their stay. In its 2001 report “Crossing the quality chasm: A new health system for the 21st century,”² the Institute of Medicine identified *failure to rescue*—first defined by Silber in 1992 as hospital deaths following adverse occurrences such as post-surgical complications³—as a primary patient safety target.

The Anesthesia Patient Safety Foundation in “Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period” conference summary stated that, “The consensus of conference attendees was that continual electronic monitoring should be utilized for inpatients receiving postoperative opioids.”⁴

Patient surveillance or continuous monitoring on normally unmonitored wards⁵ is a departure from the concept of optimized individual care to optimized population care. It is a necessary conceptual

paradigm shift for anesthesiologists, but common practice in preventative medicine. This change in approach became necessary because of the documented failure of successfully identifying patients at risk for adverse events.⁶ Historically, postoperative monitoring was electively used on some patients perceived to be at a particular risk (e.g., patients with sleep apnea), a strategy based on condition monitoring. Equally important, retrospective reviews demonstrated that adverse events are preceded by a period of physiologic instability of 6-8 hours.^{7,8} Therefore, identification of at-risk patients by spot checks every 6 hours for 10 minutes, which observes vital signs only 5% of the time, begs for improvement. Hence, patient surveillance was introduced with the full understanding that we must do better. While monitoring cannot prevent all physiologic deterioration, it can function as a “patient safety airbag.”

Patient surveillance (PS) is still in its infancy. While there are initial encouraging results,⁹ there are some common misunderstandings regarding the concepts and many questions remain. Thus, we appreciate the invitation by the APSF to provide more

information in this newsletter on our use of patient surveillance since 2007.

In this report we will summarize the Dartmouth experience in the following areas:

- Are alarm settings for heart rate (HR) and oxygen saturation (SpO₂) transferable among different surgical populations, or even between surgical and medical populations?
- Were our initially reported results reproducible on other units?⁹
- Is patient surveillance cost-effective?
- What are the next steps we should implement?

Universal Alarm Settings?

Patients on medical and surgical floors show remarkable similarities regarding their physiological status. Knowledge of these similarities allows the use of similar static alarm settings when introducing patient surveillance systems. Only minor observable

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Survey Suggests Viewing the APSF Fire Safety Video Changed Practice Among Anesthesia Professionals

by Robert K. Stoelting, MD, President APSF

In February 2010, the Anesthesia Patient Safety Foundation (APSF) announced the availability of complimentary copies of the 18-minute educational DVD, *Prevention and Management of Operating Room Fires* that was produced in association with ECRI Institute.¹ A principal objective of the APSF fire safety video was to emphasize the potential role of supplemental oxygen in surgical flash fires.

Between February 2010 and November 22, 2011, APSF received 3677 online requests for the APSF fire safety video and 587 of those requesting the DVD listed their professional degree as MD, DO, or CRNA.

To evaluate the impact of this educational video on how anesthesia professionals (MDs, DOs, CRNAs) approached the administration of supplemental oxygen to “at risk patients” (operations above T5 utilizing an ignition source in proximity to an oxidizer-enriched atmosphere),² APSF sent an anonymous electronic survey (24 questions, estimated completion time less than 4 minutes) to those 587 individuals classified as anesthesia professionals.³



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APSF Fire Safety Video Sparks Changes in Practice

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Ultimately, APSF could confirm delivery of the survey to 541 anesthesia professionals. A total of 167 responses (initial and second request) were received for a response rate of 30.9%.*

Based on the survey responses, APSF believes the fire safety video "changed practice" and had an impact on "how anesthesia professionals administered supplemental oxygen and managed the airway" in at risk patients.

Before viewing the APSF fire safety video, 37.8% of respondents indicated they would administer supplemental oxygen by open delivery if needed to maintain an acceptable arterial oxygen concentration in patients undergoing operations above T5 (i.e., at risk for surgical fires) (Figure 1). Furthermore, only 12.8% of respondents indicated they would secure the airway in

such patients (Figure 1). After viewing the APSF fire safety video, only 1.8% of respondents indicated they would administer supplemental oxygen by open delivery to "at risk patients" if needed to maintain an acceptable arterial oxygen concentration, whereas 42.3% now indicated they would secure the airway (LMA, endotracheal tube) in these patients (Figure 2).

When asked if "securing the patient's airway introduced more risk than did supplemental oxygen (greater than 30%) with a natural (unsecured) airway" in those patients considered to be at risk for surgical fires, 24.5% answered "Yes" and 75.5% answered "No."

When asked if the APSF fire safety video changed how they selected patients to receive supplemental oxygen, 79.3% responded "Yes" (Figure 3) and 91.5% agreed the fire safety video helped them identify patients at risk for surgical fires (Figure 4).

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Figure 1

Before viewing the APSF fire safety video, what was your approach to "at risk patients" requiring supplemental oxygen to maintain an acceptable arterial oxygen concentration?

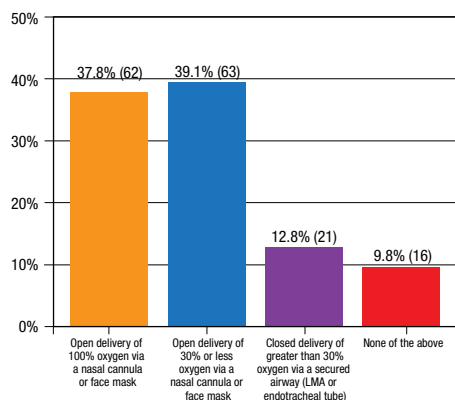


Figure 3

Did viewing the APSF fire safety video change how you select patients to receive supplemental oxygen?

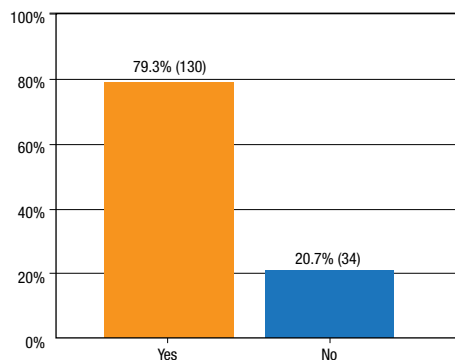


Figure 2

After viewing the APSF fire safety video, what is your approach to "at risk patients" requiring supplemental oxygen to maintain an acceptable arterial oxygen concentration?

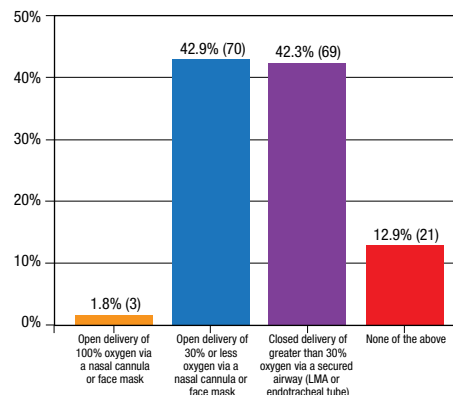
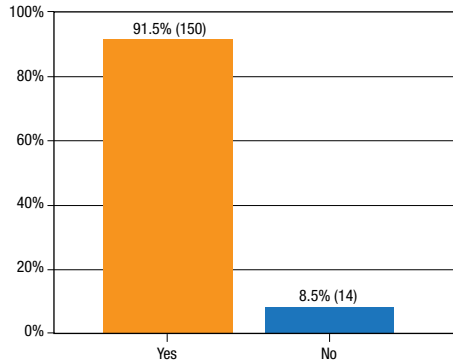


Figure 4

Did viewing the APSF fire safety video help you identify "at risk patients" for operating room fires?



NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation



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Postoperative Monitoring Improved Outcomes

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differences exist between different surgical and medical wards (Table 1, Figures 1 and 2). Patients spent about 6% of the time with oxygen saturations of <90% and 13% at <93% SpO₂. Heart rates were >80 bpm 50% of the time for all units; in medicine 14% of the time was spent >100 bpm, while in surgery the figure was 11%. Mean SpO₂ and HR were very similar among surgical units and between surgical and medical wards.

With the exception of the pediatric unit, we used the same alarm settings as in our original description (SpO₂ <80%, HR <50 or >140),⁹ with alarm adjustments by nursing staff of ±10%, and further adjustments with a physician order. All medical and surgical patients at Dartmouth have been continuously monitored since 2010.

Results on Other Units

Expansion of patient surveillance using SafetyNet™, Version 2.0.1.3 (Masimo Corp., Irvine, CA) to other units had positive effects on outcomes on all surgical, but not medical units. Figure 3 demonstrates a reduction in average rescue events on the surgical units. This was accompanied by a reduction in care escalations to units of higher intensive care (intermediate and intensive care units), as seen in Figure 4. We use rescue events identified as Rapid Response Team (RRT) activations for cardiopulmonary and respiratory arrests as our main measure of success of early intervention prompted by continuous monitoring. In contrast to measuring escalation of care to intermediate or intensive care units (ICU), the triggering of the rescue team is not dependent on resource availability (ICU beds) or institutional practice patterns. Therefore, we find reduction of rescue events to be a more meaningful measure of early interventions that also makes comparisons among institutions possible.

We have seen institutional reductions in rescue events (0-65%) and in ICU transfers (0-50%). Greater reductions are seen on wards with higher utilization of the system, greater baseline risks, and higher opioid consumption. Use of opioids and number of opioid reversals have not changed (Table 2); opioid antagonists are given for respiratory rates of 5 or less and are administered by nurses per our protocol. However, no patients have suffered irreversible severe brain damage or died since PS was instituted on the original study unit in December of 2007 as a result of respiratory depression from opioids. On surgical units, opioid consumption is greater than on medical units, and the majority of rescue events (>75%) are respiratory in nature.

These results have prompted our institution to mandate continuous monitoring of all patients when they are not being directly observed by a health care provider. If patients refuse such monitoring, they are asked to acknowledge the increased risk using an institutional refusal form.

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Table 1: Comparison of 3 Surgical Units.

	General Surgery (%)	Orthopedic (%)	Vascular-Thoracic (%)
SpO ₂ <93%	12	13	15
SpO ₂ 93-97%	56	53	59
SpO ₂ >97%	32	33	26
Heart Rate 60-79	38	46	50
Heart Rate 80-99	46	43	40
Heart Rate 100-119	14	10	9
Heart Rate ≥120	2	1	1
2-4 Patient days	733	1940	1818
Data points	63,356,247	167,655,437	157,108,126
Mean SpO ₂ [SD]	95.8 [±3.0]	95.8 [±3.3]	96.5 [±3.1]
Mean Heart Rate [SD]	82.5 [±16.5]	80.6 [±15.1]	78.7 [±15.4]
DRG index	1.44	2.0	1.92

SD: standard deviation. DRG index: diagnosis related group relative weight index (an indicator for severity of illness with higher numbers reflecting higher severity).

SpO₂ Histogram Comparison

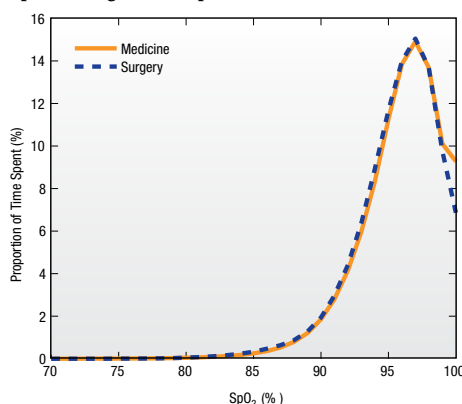


Figure 1: Distribution of oxygen saturation by pulse oximetry comparing patients on surgical and medical units.

HR Histogram Comparison

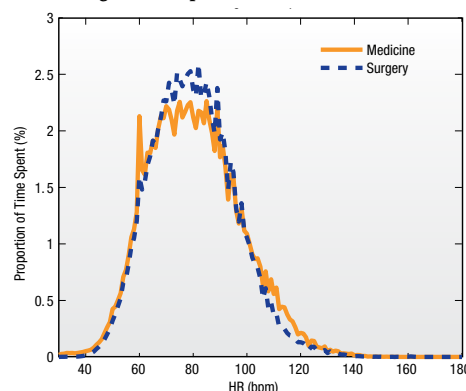


Figure 2: Time spent in heart rate states comparing patients on surgical and medical units.

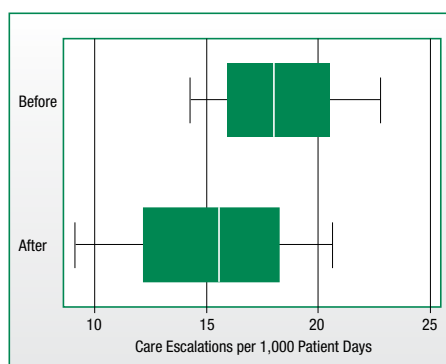


Figure 3: Rescue events (Rapid Response Team activations, arrests, and respiratory codes) per 1,000 patient days per month over 2 years with patient surveillance deployment after 12 months on 3 surgical units. Box plots: white line displays median, dark boxes contain 25-75% percentiles, whiskers 5-95% percentiles. Wilcoxon rank sum test $p < 0.05$ for all surgical units.

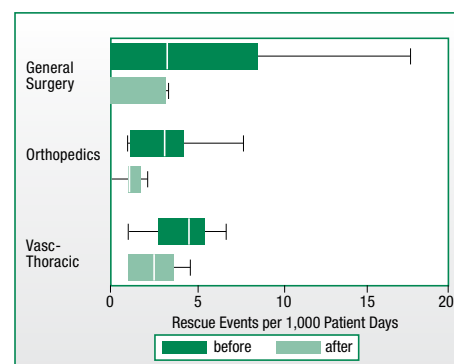


Figure 4: Care escalations (Transfers to Intermediate or Intensive Care Units) per 1,000 patient days per month in the 12 months before and after implementation of patient surveillance. Box plots: white line displays median, dark boxes contain 25-75% percentiles, whiskers 4-95% percentiles. Wilcoxon rank sum test: $p = 0.02$.

Patient Acceptance and Cost-Effectiveness Are Key Factors

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Cost-Effectiveness

We also conducted a cost-effectiveness analysis for continuous patient monitoring. The costs we used included hardware costs, hospital charges, and fees, and should be considered estimates. These costs are dependent on institutional factors such as volume purchasing and discounts and would vary from institution to institution. The cost-effectiveness depends upon the impact of patient surveillance. For purposes of simplicity, the model presented here is based on reduction of ICU transfers and days spent in ICU. We do not try to estimate other cost opportunities such as medicolegal cost or reduced utilization of rapid response teams, nor did we use a financial penalty for adverse outcomes as is commonly done in cost-effectiveness studies. These potential costs could dramatically increase the cost savings shown in this article. The study of the relationship of quality improvement and cost savings is complex; thus, we are giving a broad overview of *cost opportunity* without trying to attempt an estimate of various levels of realizable cost reductions.¹⁰

Initial implementation costs for a 36-bed unit amounted to \$167,993 (Table 3), plus annual costs of \$58,261 (Table 4). The cost per patient per hospital episode is \$85 for the implementation year and \$22 for subsequent years. Averaged hospital costs for a patient on the original study unit without an ICU Transfer were \$17,585 vs. \$76,044 with an ICU transfer (Table 5).

Prior to introduction of patient surveillance the length of stay (LOS) of a patient with ICU transfer was 24.39 days (7.67 days in ICU plus 16.72 days on the regular floor), afterwards average LOS was 19.32 days (5.87 days in ICU plus 13.45 days).

Annual opportunity cost savings¹¹ due to decreased ICU transfer rate amount to \$1,479,012 for the initial study unit (as described in reference 9). These opportunity cost savings at DHMC helped address the ICU capacity limitations that were leading to missed opportunities to care for patients in addition to the financial impact. On the other end of the spectrum we had increased cost in a medical unit where the introduction of surveillance was not associated with any change in outcome (implementation and ongoing maintenance costs of the system).

Sensitivity Analysis. Varying the baseline ICU transfer rate demonstrated a greater effect of using patient surveillance as the baseline ICU transfer rate increases. Varying the relationship between ICU transfers with and without PS showed equality when the rate (per 1000 patient days per month) of ICU transfers on the patient surveillance unit is 1.09 (9% higher) that of the non-PS unit.

Cost-effectiveness on other units depend primarily on incidence of adverse events and reduction of event rate. Our thoraco-vascular unit had a higher baseline event rate than the original study unit with a smaller reduction of ICU transfers by about 30% and rescue

events by 50%. Because of the higher incidence of transfers, a total of 168 days in the ICU were saved in the 12 months after implementation of PS compared to before, about 10 more days than the original study unit. On some medical units with low event rates and smaller or no change with PS, cost-effectiveness is neutral or even negative when using this opportunity cost-based analysis. Due to high utilization of patient bed capacity (98% at DHMC), standard bed monitoring capacity in all medical and surgical beds allows a flexible floating team of nurses that can provide care for patients on a temporary, as-needed, basis. This flexibility assists our management of our entire inpatient census.

Next Steps

Despite our best efforts, patients still have adverse events requiring rescue interventions and escalations of care. PS as an airbag has worked; we have had no death on the original PS unit since 2007.

We are investigating the use of acoustic respiratory monitoring in addition to our current pulse oximetry network to determine if it has an impact on overall outcome and to identify population groups at risk that would have the greatest benefit from additional monitoring (such as postoperative patients on supplemental

oxygen). Early results show that the monitors are relatively well-received by patients. These monitors are better tolerated than our earlier trials in the immediate postoperative phase with chest straps for respiratory rate monitoring or nasal cannulas for end tidal CO₂ monitoring, but not as well as finger pulse oximeter probes. Patient comfort and acceptance and minimizing false positive alarms are of great importance when evaluating continuous surveillance devices. In the future we will likely see pulse oximetry surveillance for all, and additional monitoring for some until monitors with the accuracy and comfort of pulse oximetry become available.

Static alarm triggers need to be combined with smart alarms, which have the ability to identify and track patterns associated with clinical deterioration. Our early results are encouraging, while the ability to identify patients likely to deteriorate remains challenging. In a recent roll-out of continuous monitoring in a pediatric unit we have started to use patient dependent alarm settings (age-dependent heart rate alarms). Ideally, systems could be integrated and exchange information between electronic record systems and bedside monitors to allow the seamless calculation of early warning scores based on physiologic, demographic, and

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Table 2: Rescue Events (RRT activations, arrests and respiratory codes) per 1,000 patient days per month over 2 years with patient surveillance deployment after 12 months on 3 surgical units. Morphine equivalents in mg per patient per month. Opioid Reversals per 1,000 patient days.

	Before [mean (SD)]	After	p Values
Rescue events	4.4 (3.9)	1.90 (1.7)	p<0.01
Morphine equivalents	21.2 (3.8)	24.9 (6.5)	NS
Opioid reversal	1.6 (1.8)	1.8 (1.6)	NS

SD: Standard Deviation. Statistics by Wilcoxon rank sum test.

Table 3: Fixed Costs

36 bedside devices, connectors, cables, SafetyNet™ for 36 instruments, pagers, vendor installation cost

Item	Cost (\$)
Surveillance System for a 36-bed unit	165,493
Training	2,500

Table 4: Annual Costs for Surveillance System

Item	Cost (\$)
Implementation and Continuing Operations. Implementation: 2.5 hours per bed, 3-4 hours per unit, Operation: 2 hours per week per unit (65-70 hours)	8450
Implementation and Operation of wireless pager system	3380
Patient Surveillance System Consumables (8.25 per unit with 469 sensors on average per month)	46431

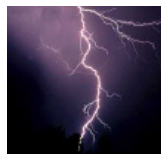
Table 5: Average Hospital Costs Per Patient on Original Study Unit

Costs	Average (\$)	SD	CI
With transfer to ICU	76,044	71,847	60,770-91,319
No transfer	17,585	10,608	17,129-18,041

ICU: Intensive Care Unit, SD: Standard Deviation, CI: 95% Confidence Interval

NATIONAL ALERT NETWORK (NAN)

March 20, 2012



This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

Potential for wrong route errors with **Exparel** (bupivacaine liposome injectable suspension)



This alert is being issued to inform health professionals about a potential medication safety issue with Exparel (bupivacaine liposome injectable suspension): wrong route of administration errors if the drug is confused with propofol.

Exparel is a local anesthetic that is infiltrated into a surgical wound during a surgical procedure to produce postsurgical analgesia. It is not intended for systemic use. Exparel is a milky white suspension similar in appearance to propofol emulsion. When prepared in syringes, these products essentially look identical. If Exparel is accidentally administered intravenously instead of propofol, toxic blood concentrations might result, and cardiac conductivity and excitability may be depressed, which may lead to atrioventricular block, ventricular arrhythmias, and cardiac arrest.

Propofol is used as an anesthetic during surgical procedures and as a sedative during procedures or for patients undergoing mechanical ventilation. Thus, Exparel and

propofol may both be used in similar healthcare settings.

Based on analysis of other medication errors that ISMP has received through various sources, including the ISMP National Medication Errors Reporting Program, similar looking drug vials and unlabeled syringes are often identified as root causes of medication errors. There is reason to believe such mix-ups are possible with Exparel and propofol. The concern about unlabeled syringes is well founded in this case, as some practitioners in the operative setting have long held the now false belief that

propofol is the only white milky parenteral medication one sees in surgical settings. Today, there are several parenteral medications and other fluids that are white emulsions, leaving any unlabeled syringe an extremely dangerous proposition.

Exparel vials have an elongated shape and neck size and may feel different when in hand. While the teal and white package colors are



specific to Exparel, some propofol vials also have teal and white colors or blue and white colors that may be difficult to differentiate from an Exparel teal label, especially in poorly lit areas or by individuals who have difficulty perceiving certain colors. The 20 mL

volume of Exparel vials is similar to that of some propofol vials. A bold statement that Exparel is for infiltration only appears on the label but may not be noticed by all users.

To date, neither ISMP nor FDA has received any medication error reports of mix-ups between Exparel and propofol. Therefore, this NAN alert is intended to help healthcare facilities preempt serious medication errors by implementing these recommendations wherever both products may coexist:

1. Separate the storage of propofol and Exparel vials in the pharmacy and in all clinical settings where the drugs may be stocked.
2. Specifically remind staff to never leave any syringe of medication

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NATIONAL ALERT NETWORK (NAN)

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March 20, 2012



This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

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or solution unlabeled. The general rule for safety is to label any prepared syringe or solution if it is not administered immediately or if it may leave the preparer's hands. However, the high risk of mix-ups between unlabeled syringes of propofol and Exparel and the subsequent risk of patient harm suggest that more stringent precautions are needed with these two medications. In the operating room or in other surgical areas where Exparel and propofol may both be used, all syringes of these medications prepared by a scrub nurse, circulating registered nurse, anesthesia staff, or surgeon should be labeled, even if the medication will be immediately administered (propofol) or infiltrated into the surgical site (Exparel).

3. As an added precaution, the circulating registered nurse should establish a routine double check to make sure any unused medication in a syringe containing Exparel never leaves the sterile field without a label.

4. To facilitate proper labeling within a sterile field, hospitals should provide sterile labels to affix to prepared syringes of all medications.

5. It is dangerous to leave an unlabeled syringe of any drug on a counter, in a cart drawer, or anywhere else. If found, the contents of any unlabeled syringe should be discarded immediately.

6. For patient safety, hospital medication labeling practices should be subject to ongoing monitoring.

7. Immediately distribute this alert to healthcare practitioners, particularly those who work in surgical settings such as operating room nurses, pharmacists, anesthesia staff, and surgeons.

www.asra.com/checklist-for-local-anesthetic-toxicity-treatment-1-18-12.pdf. The organization that provides this checklist, the American Society of Regional Anesthesia and Pain Medicine, also suggests making a local anesthetic toxicity



kit available in key areas.

8. Ensure that directions for treatment of bupivacaine toxicity are readily available in all surgical areas where Exparel may be used. A helpful checklist for the treatment of local anesthetic system toxicity can be found at:

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCCMERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.

The Anatomy of the Drug Shortages

by Tricia Meyer PharmD, MS

The number of drug shortages in the U.S. has steadily risen to approximately a 4-fold increase from 2006 (70 drug shortages) to 2011 (267 drug shortages). With already 30 drug shortages being reported for the first 2 months of 2012, the drug shortage dilemma will likely continue. The majority of the drug shortages have involved injectable or parenteral drugs (63% in 2010, 58% in 2011) which has placed the heaviest burden on hospitals, infusion clinics, and surgical/anesthesia areas. Although no drug class has eluded the drug shortage list, the practices of oncology and anesthesiology have had significant drug supply disruptions over the past 2-3 years. The central nervous system (CNS) drug class had the highest number of drug shortages as compared to other drug classes for 2010. The trend has continued for 2011 with CNS agents being most prevalent followed by antibiotics, chemotherapy, and cardiovascular and autonomic agents on the drug shortage list.¹⁻³

Drug shortages have numerous implications for the institution, providers of care and patients. These include adversely affecting choices for drug therapy, delaying medication therapies or treatments, escalating costs of product and resources to manage shortages, and increasing risk for medication errors and untoward patient outcomes. There also exists an emotional component to the drug shortages of frustration, anger, anxiety, and mistrust that results in strained relationships between the providers and manufacturers; pharmacy and prescribers; patient and providers.^{4,5}

The factors surrounding supply disruptions are multifaceted, involved, and complicated. The supply chain of a drug will typically include multiple stakeholders, such as suppliers of the raw material, manufacturers, regulators, wholesalers/distributors, prime vendors, group purchasing organizations, and the health care system. The supply disruptions can occur at any point in the supply chain. Many times the reason for drug shortages is not disclosed. According to the University of Utah Drug Information Service, 54% of the drug shortages in 2011 did not have an identified reason for the supply disruption.²

Although raw materials were not cited as one of the primary reasons for drug shortages in 2011 (3%), it has been a significant concern in the past such as the heparin raw ingredient contamination several years ago.² Serious adverse events, including deaths, were reported leading to product recalls and a shortage of heparin.⁶ The majority (80%) of raw materials or active product ingredients (API) come from countries

Obama To Announce Drug Shortage Resolution

A front-page story in the *New York Times* (10/31/2012, A1, Harris) reports, "President Obama will issue an executive order on Monday that the administration hopes will help resolve a growing number of critical shortages of vital medicines used to treat life-threatening illnesses, among them several forms of cancer and bacterial infections." The order "instructs the FDA to do 3 things: broaden reporting of potential shortages of certain prescription drugs; speed reviews of applications to begin or alter production of these drugs; and provide more information to the Justice Department about possible instances of collusion or price gouging." The *Times* notes that it is "a modest effort that, while possibly helpful, is unlikely to resolve the problem soon or entirely."

http://www.nytimes.com/2011/10/31/health/policy/medicine-shortages-addressed-in-obama-executive-order.html?_r=1, accessed May 1, 2012

Anesthesiologists Find Growing Drug Shortage

Medscape Today (10/29/2012, Helwick) reported, "Drug shortage is an issue throughout the health care system today, but it is particularly concerning for anesthesiologists, because more central nervous system (CNS) drugs are in short supply than any other class of drugs." And "the Drug Shortage Survey of 1373 ASA members conducted in April revealed that 90% of respondents reported a shortage of at least 1 drug and 98% had experienced a shortage during the previous 12 months."

<http://www.medscape.com/viewarticle/752541>, accessed May 1, 2012.



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Manufacturing Difficulties Are Common Cause of Drug Shortages

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outside of the U.S.¹ The global outsourcing of raw materials can be affected by political unrest and conflict in the country, which can interrupt trade; animal diseases that contaminate tissue where raw materials are obtained; raw material degradation, inclement weather, and other environmental conditions that can impact the growth of plants used for raw material. Hurricanes, fires, tornados, tsunamis, and floods can play an additional role of not only destruction of the raw material but also damage to the raw material facility and obstruction of product transportation.⁷ The earthquake in Japan has contributed to circumstances leading to several potential shortages, and the Icelandic volcano caused transportation delays resulting in product delays.⁸

The most commonly identified understood reason for drug shortages in 2011 was manufacturing difficulties. The Food and Drug Administration (FDA) can halt or delay production when noncompliance with current good manufacturing practices (cGMP) occurs. Setbacks caused by older equipment, reallocation of resources away from the manufacturing facility, loss of knowledgeable staff in production/compliance issues due to mergers, and cGMP problems with subcontractors (a subcontractor may supply to one or all of the manufacturers of that product) may also contribute to drug shortages. The lack of resources and staffing from FDA to conduct inspections in a suitable time can also cause delays.^{1,7}

A supply disruption can occur based on corporate decisions by the manufacturer. This may occur when the manufacturer changes formulation which may delay product availability during the transition. Additionally, business decisions are made by the

manufacturer that may cause supply disruptions such as shifting their production efforts to another product, discontinuing manufacturing of a product because of inadequate financial returns or delaying production because of the need for a large investment to correct a manufacturing issue. Market approval requirements and post marketing surveillance may cause a shortage due to the manufacturers limiting the available supply. In some circumstances providers and selected suppliers can only obtain product by fulfilling the manufacturer's requirements. Voluntary recalls from the pharmaceutical manufacturers can also cause a drug shortage. These recalls will normally involve specific lot numbers and may have a temporary effect on the market. The voluntary recalls are based on lack of assurance for product safety or for technical difficulties such as labeling changes.⁷ The early propofol shortage was based on recalls and also contributing to the shortage was the departure of one of manufacturers from the market.⁹ Drug shortages can also occur when companies merge. This may include decisions to limit the product lines or move production to a different facility. A small number of companies supplying the same drug can be very challenging when one or more has a supply disruption. Even more problematic is a pharmaceutical company that is the sole manufacturer of the product and develops difficulty supplying the drug.⁷

In a recent conference with key stakeholders experiencing drug shortages, pharmaceutical manufacturers attributed some of the burden of drug shortages to the FDA's Unapproved Drugs Initiative. Interestingly, these are drugs that have entered the market and were only reviewed by FDA for their safety. FDA rules were later expanded to require that the drug be effective and that the manufacturing

processes and labeling meet with FDA requirements. Submission of the drug application for the approval of these older drugs is lengthy and expensive. In 2006, the FDA began removal of these unapproved drugs from the market if they failed to comply with the evidence-based system of drug approval.¹⁰

Another problem in drug shortages is the lack of notice and the limited time to prepare for the unavailability of product. Adding to this difficulty is lean or tighter inventory levels at almost every step of the drug supply chain. This practice is called “just in time” inventory management and is used by raw product suppliers, manufacturers, distribution centers, and pharmacies. For example, a typical hospital pharmacy may only have a 4-day inventory of drug on their shelves and order this drug on a daily or every other day schedule to replenish this inventory. When a shortage occurs, the hospital will have minimal stock on its shelves and therefore a reduced time to prepare for alternatives. The “just in time” inventory is an established means to lower the cost of inventory on hand and increase cash flow for the center.^{7,11}

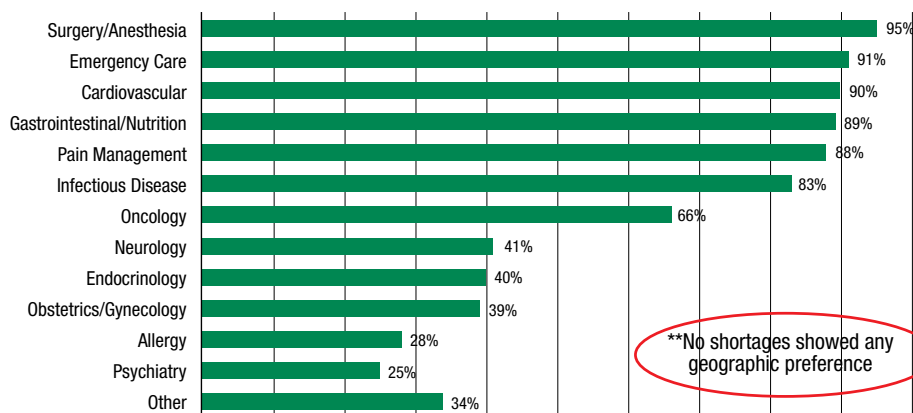
Drug shortages can also occur based on an increase in the demand of the product that is greater than the current supply. This can happen when a new indication is approved for an existing drug, new therapeutic guidelines recommend use of the drug, or an outbreak of a disease prompts the increased use of a drug. As an example, during the Swine Flu outbreak, Tamiflu® (oseltamivir) was difficult to obtain based on the increased demand of the drug's indication to prevent or treat the flu.

Financially, drug shortages drain already limited budgets in a medical facility. Alternative or therapeutically equivalent drugs can cost more than the drugs involved with the supply disruption.¹¹ A further crisis occurs when the sudden demand for the alternative drug occurs and this can cause a secondary shortage.

Once the drug becomes unavailable or limited in supply, resources are needed at the facility to locate different suppliers, prioritize the allocation and location of the remaining stock, investigate the use of other therapeutic products, and communicate the information to staff. When an alternative drug is used, the simple questions of dosage, frequency, preparation, administration, side effects, contraindications, drug interactions, monitoring parameters, and storage requirements are very necessary information. Without this information there may be an increased risk for drug errors. Other causes of errors relate to differing manufacturers, drug strengths, packaging—however, it is only available from a different manufacturer, or has a different strength, packaging, dosage form or volume. Because of the number of supply disruptions and ongoing nature of this

Hospitals report experiencing drug shortages across all treatment categories

Percentage of Hospitals Experiencing a Drug Shortage by Treatment Category



Sources:
AHA survey of 820 non-federal, short-term acute care hospitals; data collected in June 2011.

AHA Survey Drug Shortages

See “Drug Shortages,” Page 18

New Anticoagulants Present New Challenges

by Rajnish K. Gupta, MD

In the last decade, several new anticoagulation medications have become available on the market. Table 1 summarizes several of these new drugs as well as relevant pharmacologic data. Primarily these

agents are being used for stroke prevention in patients with atrial fibrillation or for the prevention of venous thromboembolic events (VTE) in the perioperative period. The appeal of many of these agents to our colleagues and patients is their ease of

administration, with once or twice daily dosing, and the lack of need for therapeutic monitoring. The newest agents are orally administered as well.

See "New Anticoagulants," Page 17

Table 1. Listing of several relatively new anticoagulant and antithrombotic agents along with relevant pharmacologic data.

Generic	Brand	Year	Mechanism	Indications	Route	Half-life	Regional Timing	Metabolism	Excretion	Monitoring	Antidote
Rivaroxaban	XARELTO	2011	Selective, non-AT-III dependent Factor Xa inhibitor	Prevention of VTE and stroke	PO	5-9 hrs	None listed.	Hepatic; CYP450 drug interactions	Renal and GI	None required. Rivaroxaban-calibrated PT or anti-Factor Xa assay can be used.	None officially. Possible value of Prothrombin complex concentrate infusion
Tricagrelor	BRILINTA	2011	P2Y ₁₂ ADP receptor platelet inhibitor	Reduce risk of thrombotic events in patients with Acute coronary syndrome	PO	7 hrs for tricagrelor; 9 hrs for active metabolite	Recommended to stop more than 5 days before surgery	Hepatic; CYP3A4/5 drug interactions	Hepatic metabolism; no renal excretion	None.	None.
Dabigatran	PRADAXA	2010	Direct thrombin Inhibitor	Prevention of VTE and stroke	PO	12-17 hrs	None officially. Typically wait 2-3 half-lives to allow drug to be cleared.	Minimal	Renal	None required. aPTT and thrombin time can provide qualitative information. INR is not useful.	None. Combination of charcoal and dialysis to reduce drug content; blood transfusions to control bleeding.
Prasugrel	EFFIENT	2009	P2Y ₁₂ ADP receptor platelet inhibitor	Reduce risk of thrombotic events in patients with Acute Coronary Syndrome managed by PCI	PO	7 hrs (2-15 hrs)	Recommended to stop 7-10 days before surgery (irreversible platelet inhibition)	Hepatic	Renal and GI	None.	Platelet transfusions
Desirudin	IPRIVASK	2003	Thrombin inhibitor	Prophylaxis for VTE in hip replacement	SQ BID	2-4 hrs	Initiate after regional anesthesia; Typically wait 2-3 half-lives prior to pulling catheter; confirm aPTT	Renal	Renal	aPTT	No specific antidote; Blood transfusions are appropriate; thrombin rich plasma concentrates and DDAVP may be helpful
Fondaparinux	ARIXTRA	2001	Selective AT-III mediated Factor Xa inhibitor	Prevention and treatment of VTE	SQ Qday	17-21 hrs	Remove catheter 36 hrs after last dose; restart 12 hrs after pulling catheter	Minimal	Renal	None required. Anti-Xa levels can measure activity. PT and PTT are not useful.	None officially. Possible value of recombinant Factor VIIa (with tranexamic acid)
Tinzaparin	INNOHEP	2000	Low molecular weight heparin	Treatment of VTE	SQ Qday	3-4 hrs	Not listed.	Desulphation and depolymerization	Renal	None required. aPTT and PT are NOT useful for monitoring	Blood transfusions; protamine
Lepirudin	REFLUDAN	1998	Thrombin inhibitor	Prophylaxis for VTE in patients with Heparin-induced thrombocytopenia	IV	1-2 hrs	Initiate after regional anesthesia; Typically wait 2-3 half-lives prior to pulling catheter; confirm aPTT	Catabolic hydrolysis	Renal	aPTT	No specific antidote; Blood transfusions recommended; hemodialysis may help
Anagrelide	AGRYLIN	1997	Platelet reducing agent; cAMP PDEIII inhibitor	Thrombocytopenia, reduce risk of thrombosis	PO	1.3 hrs	Increased Platelet count in 4 days; check Platelet count before procedure	Hepatic; CYP1A2	Renal	Platelet count	Platelet transfusions

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A Checklist for Treating Local Anesthetic Systemic Toxicity

by Joseph M. Neal, MD, and Guy L. Weinberg, MD

Within the world of anesthesia-related patient safety, the permutations of complication and treatment are constantly changing. Sometimes it is an old complication that never quite goes away; sometimes it is a new treatment for an old complication; and sometimes we find a new way of managing the intersection of complication and treatment. Such is the current state of local anesthetic systemic toxicity (LAST). Anesthesiologists and certified nurse anesthetists have dealt with this complication since the introduction of local anesthetics over a century ago, yet despite advances in pharmacology and the development of techniques to detect and prevent local anesthetic overdose, mild LAST still occurs in about 1:1000 patients. Seizures manifest in 0-25:10,000 patients, while cardiovascular instability and/or cardiac arrest occur in a smaller fraction of patients. The development of lipid emulsion therapy has brought a powerful antidote that adds value to the time-honored therapies of oxygenation and seizure control. We now embrace the concept that checklists can actually help us manage this rare but potentially fatal complication, the modern treatment of which relies on administering a seldom used solution whose dosing guidelines are not readily available in most anesthesiologists' memory banks.

In 2008 the American Society of Regional Anesthesia and Pain Medicine (ASRA) convened its second practice advisory panel on LAST. The 2010 executive summary¹ of that panel's findings can be downloaded for free from the ASRA website (www.asra.com). Amongst other salient findings, the practice advisory panel noted that the presentation of LAST is often different from the classic textbook description of mild subjective symptoms (auditory changes, circumoral numbness, dizziness) that progress to systemic excitation (seizure, ventricular arrhythmias, hypertension), which then evolves into systemic depression (asystole, cardiac collapse).² Less than 40% of patients will present with this classic prodrome. Instead, some will proceed directly to seizure with little or no warning signs, fewer will present with cardiac arrest alone, and a significant number will present 5 to 30 minutes after local anesthetic injection with non-descript signs of altered mental status, bradycardia, or hypotension. The obvious implications for clinicians (including non-anesthesia providers) who use potentially toxic doses of local anesthetic are that all patients should be observed with standard monitors for at least 30 minutes after block placement, and resuscitation equipment should be readily available. Moreover, we must heighten our vigilance in those patients who have a lower-than-normal threshold for local anesthetic toxicity: extremes of age, and/or underlying cardiac, hepatic, neurologic, or metabolic co-morbidities.

A key component of the ASRA practice advisory was the creation of a treatment checklist³ (Figure 1), a

copy of which can also be obtained from the ASRA website. The front of the ASRA Checklist contains all the suggested steps for treating suspected LAST. The back of the sheet summarizes key prevention, detection, and treatment strategies. The practice advisory panel recommends that the checklist be immediately available wherever potentially toxic doses of local anesthetics are used.

The readability and usability of the ASRA Checklist was tested during a simulation exercise involving trainees at the Virginia Mason Medical Center.⁴ Key observations from that study are pertinent to all of us who may treat LAST. First, optimization of oxygen delivery and suppression of seizure

activity is of primary importance. Second, the subsequent treatment of severe LAST and resultant cardiovascular instability is different from "classic ACLS" ischemic cardiac arrest. Drugs that further depress cardiac contractility, such as local anesthetics, beta blockers, calcium channel blocks, or propofol, should be avoided. Third, animal studies suggest that "classic cardiac arrest drugs" such as vasopressin and high-dose epinephrine are counterproductive in the treatment of LAST. Use of epinephrine is preferably limited to lower doses than typically used in standard ACLS, i.e., less than 1 mcg/kg. The simulation also

See "LAST Checklist," Page 27



AMERICAN SOCIETY OF
REGIONAL ANESTHESIA AND PAIN MEDICINE

Checklist for Treatment of Local Anesthetic Systemic Toxicity

The Pharmacologic Treatment of Local Anesthetic Systemic Toxicity (LAST) is Different from Other Cardiac Arrest Scenarios

- ☐ **Get Help**
- ☐ **Initial Focus**
 - ☐ **Airway management:** ventilate with 100% oxygen
 - ☐ **Seizure suppression:** benzodiazepines are preferred; **AVOID propofol** in patients having signs of cardiovascular instability
 - ☐ **Alert** the nearest facility having **cardiopulmonary bypass** capability
- ☐ **Management of Cardiac Arrhythmias**
 - ☐ **Basic and Advanced Cardiac Life Support (ACLS)** will require adjustment of medications and perhaps prolonged effort
 - ☐ **AVOID vasopressin, calcium channel blockers, beta blockers, or local anesthetic**
 - ☐ **REDUCE individual epinephrine doses to <1 mcg/kg**
- ☐ **Lipid Emulsion (20%) Therapy** (values in parenthesis are for 70kg patient)
 - ☐ **Bolus 1.5 mL/kg** (lean body mass) intravenously over 1 minute (~100mL)
 - ☐ **Continuous infusion 0.25 mL/kg/min** (~18 mL/min; adjust by roller clamp)
 - ☐ Repeat bolus once or twice for persistent cardiovascular collapse
 - ☐ Double the infusion rate to 0.5 mL/kg/min if blood pressure remains low
 - ☐ **Continue infusion** for at least 10 minutes after attaining circulatory stability
 - ☐ Recommended upper limit: Approximately 10 mL/kg lipid emulsion over the first 30 minutes
- ☐ **Post LAST events at** www.lipidrescue.org and report use of lipid to www.lipidregistry.org

Figure 1. Used with permission of ASRA.

Take an Aspirin and I'll (Safely) Put You On-Call to the OR in the Morning

Robert A. Peterfreund, MD, PhD

Aspirin (acetylsalicylic acid, ASA) has a long, remarkable history in the development of useful drugs from herbal or vegetable sources. In ancient times, extracts of willow (Latin: *salix*) tree bark were used for therapeutic purposes. Early documentation appears on a Sumerian tablet dating from ~2000 BCE. The first known documentation of willow bark as an analgesic appears in the Ebers Papyrus, a medical text written in about 1540 BCE. Later, Greeks, Romans, Arabs and Chinese used willow bark preparations for their anti-inflammatory properties.

Fast forward to the 1800s when chemists characterized the medicinally active substance of willow tree bark, called salicin. From this starting material, salicylic acid was created. The common meadow-sweet flower (*Spiraea ulmaria*) contains a similar compound in abundance. Gastric side effects limited therapeutic use of salicylic acid. However, several chemists prepared a derivative, acetylsalicylic acid, which was much more clinically useful as a pain reliever and antipyretic. The Bayer chemical and pharmaceutical company marketed this substance named "Aspirin" ("A" for acetate, "spir" for *Spiraea*, with the ending "in" to facilitate enunciation). Aspirin played an important therapeutic role in the Spanish flu epidemic of 1918-1919 while becoming one of the most widely used drugs of the 20th century.

In the 1940s, California family physician Lawrence Craven observed excessive bleeding in tonsillectomy and adenoidectomy patients taking aspirin as an analgesic. In the conceptual context that thrombosis might be a cause of myocardial infarction (MI), Craven prescribed aspirin to his patients. He reported that in this cohort (no control group) receiving even small doses of prophylactic aspirin, the incidence of MI was reduced or eliminated. He also reported an apparent reduction in the occurrence of cerebrovascular events. These findings were not immediately introduced into routine practice until more definitive studies, including meta-analyses, produced comparable results.

Several investigators found that aspirin exerted antithrombotic effects by inhibiting platelet aggregation. The biochemical mechanism accounting for this action was subsequently identified: irreversible inhibition of cyclooxygenase-1 (COX-1), an essential enzyme in the pathway generating prostaglandins including thromboxane A₂, a key factor in platelet activation and thrombus formation. Since platelets lack the cellular machinery to produce COX-1, restoration of platelet function depends on generation of new platelets. This process takes several days.

Fast forward again to the current era where aspirin, sometimes in conjunction with clopidogrel, is a mainstay in antiplatelet therapy to prevent thrombosis. Some patients considered to be at low risk for developing cardiovascular disease take aspirin to

prevent new coronary or peripheral vascular thrombosis (primary prophylaxis). Patients with documented vascular disease (e.g., history of MI or stroke, peripheral vascular disease) take aspirin to prevent further events (secondary prophylaxis). In particular, patients with coronary stents take aspirin as secondary prophylaxis to prevent occlusion of the devices. Furthermore, patients with certain medical conditions (diabetes mellitus, congestive heart failure, renal insufficiency) are deemed to be at high risk for vascular disease; they also take aspirin as secondary prophylaxis.

Concern for increased bleeding led to a generally accepted practice of stopping antiplatelet therapy 5-10 days before a surgical or invasive procedure. While surgical bleeding may be increased with ongoing aspirin therapy, the risk of associated hemorrhagic morbidity and mortality remains modest for most procedures. Indeed, there is an enhanced risk of thrombosis with early withdrawal of antiplatelet therapy in medical patients following acute coronary syndromes, cerebrovascular accidents, or the insertion of vascular stents. In the setting of surgery, with attendant acute procoagulant and proinflammatory consequences, acute withdrawal of aspirin therapy may enhance the likelihood of thrombosis, thereby increasing the risk of cardiovascular morbidity and mortality.

We lack adequate studies for every procedure in every surgical specialty. However, except in some specific circumstances, the cardiovascular risk from acute aspirin withdrawal likely outweighs the risk of surgical complications from bleeding. Recent reviews conclude that aspirin should be continued up to the day of surgery for at risk patients, with few exceptions (intracranial neurosurgical procedures, intramedullary spine surgery, surgery of the middle ear or posterior eye, and possibly prostate surgery). Continuation of ASA is not viewed as a contraindication to neuraxial anesthesia. Stopping ASA therapy in secondary prophylaxis patients thus warrants thoughtful consideration in the interests of safe patient care. This decision should probably be made in conjunction with the patient's cardiologist and/or vascular physician.

At our institution, a multidisciplinary group derived a set of guidelines for managing aspirin therapy in the perioperative period. These guidelines, based on the recent literature, are intended to provide the surgeon or procedural physician a conceptual framework to aid decision making about aspirin therapy (Box). A key feature of the guidelines is the expectation that clinical decisions to stop ASA for secondary prophylaxis patients will be made collaboratively with cardiologists, vascular medicine physicians, or primary care providers who know the patient well. This approach is similar to the suggestions of Douketis et al. for secondary (high risk) prophylaxis patients, but specifies several exceptions. In contrast to the suggestion of Douketis et al.,

our institutional guidelines generally recommend continuing ASA for the primary prophylaxis (low risk) patient, again specifying several exceptions but giving discretion to the surgeon or procedural physician to stop or continue ASA therapy. Our institutional guidelines also emphasize documentation of decision making.

An overview of aspirin's history and the applications of this drug leaves several unanswered questions for safe patient management in the perioperative period:

- 1) Do we have adequate criteria to define primary prophylaxis? Stated another way, are some patients currently taking aspirin for primary prophylaxis at higher risk for cardiovascular complications than other primary prophylaxis patients?
- 2) Do we have adequate criteria to define secondary prophylaxis?
- 3) Which surgical procedures are more likely to provoke inflammatory and hypercoagulable states than other interventions?
- 4) For individual invasive procedures (in individual patients), how do we determine whether the risk of bleeding outweighs the risk of thrombotic complications? A corollary question is how to help surgeons and other procedural physicians, vascular medicine specialists, cardiologists, and anesthesiologists formulate an optimum management plan for a specific patient.
- 5) What other drugs or preparatory measures might permit the withdrawal of aspirin as an antiplatelet agent without increasing the likelihood of perioperative thrombosis? A corollary question is how can the consequences of acute aspirin withdrawal be mitigated?
- 6) How might anesthetic management (e.g., regional versus general anesthesia, the combinations of drugs used in general anesthesia) impact the propensity for perioperative thrombotic complications?
- 7) What are the advantages/disadvantages of giving aspirin (and how much) immediately before anesthesia and surgery to a high risk patient who has stopped this therapy or who has never been on aspirin?

Even after 4000 years of medicinal use, and 2 centuries of detailed chemical, biochemical, and physiologic investigation, many questions remain about willow bark extract and its derivatives in patient care. The answers have important implications for daily clinical practice and safe patient care in the perioperative period. When should our patients take aspirin, and how much, as they are placed on call to the OR in the morning?

See "Aspirin," Next Page

MGH Develops Interdisciplinary Consensus Statement

“Aspirin,” From Preceding Page

MGH GUIDELINES FOR PERIOPERATIVE ASPIRIN ADMINISTRATION

Consensus Statement from the Departments of Anesthesia, Medicine, Cardiology and Surgery

Aspirin (ASA) is prescribed for PRIMARY and SECONDARY prophylaxis to reduce adverse thrombotic events related to cardiovascular and cerebrovascular atherosclerotic disease.

PRIMARY prophylaxis can be defined as treatment with ASA in the absence of an established diagnosis of cardiovascular disease (by combination of history, exam, ECG or stress testing, ECHO, or cath lab testing). Example: an active 55-year-old male with a medical history limited to hypertension and hyperlipidemia, but no evidence of any other conditions, who takes ASA (81 mg) daily.

SECONDARY prophylaxis can be defined as treatment with ASA in the presence of overt cardiovascular disease or conditions conferring particular risk.

Examples of overt disease in the medical history or conditions conferring risk:

- atrial fibrillation
- angina
- previous MI (myocardial infarction)
- stroke
- CHF (congestive heart failure)
- CABG, PCI (percutaneous coronary intervention) or coronary stenting
- vascular surgery
- noncardiac stents (e.g. carotid, femoral, renal artery stents)
- diabetes mellitus (Type 1 or Type 2)
- renal insufficiency (Cr > 2.0 mg/dl or estimated creatinine clearance < 65 ml/min)

Management of ASA in the immediate perioperative period, based on recent literature¹⁻⁴

PRIMARY prophylaxis patients:

ASA (81 – 325 mg) should be continued in the perioperative period up to and including the day of the procedure. ASA may be held for a few days at the discretion of the surgeon or procedural physician due to a possible heightened risk for perioperative bleeding. Hold ASA in specific circumstances: intracranial, middle ear, posterior eye or intramedullary spine surgery; possibly in prostate surgery. This decision should be documented.

SECONDARY prophylaxis patients:

ASA (81 – 325 mg) should be continued in the perioperative period up to and including the day of the procedure. Exceptions: intracranial neurosurgical procedures, intramedullary spine surgery, surgery of the middle ear, or posterior eye, and possibly prostate surgery.

Stopping ASA in patients receiving the drug for SECONDARY PROPHYLAXIS needs an explicit discussion with the patient's primary care physician, cardiologist, or vascular physician. The discussion should weigh the cardiovascular risks of stopping ASA versus the risk of bleeding from the procedure. This decision should be documented.

Robert Peterfreund, MD, is an Associate Professor of Anesthesia at Harvard Medical School and an Anesthesiologist at Massachusetts General Hospital in Boston, MA.

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Letter to the Editor

Converting an Anesthesia Circuit to Deliver and Titrate Supplemental Oxygen

by Alec Rooke, PhD, MD

To the Editor:

I read with great interest the recent lead article on fire safety in the OR,¹ particularly the circumstances where a loose face mask is desired to provide supplemental oxygen. The algorithm recommends the use of a blender to provide oxygen at 30% or less. However, it is relatively simple to provide an air/oxygen mixture to a standard face mask if connected to the circuit of an anesthesia machine by large diameter tubing. Large diameter tubing is needed because the small diameter tubing from the standard face mask creates high resistance in the circuit with subsequent high pressure and activation of the continuing pressure alarm (Figure 1).

We use a standard face mask (with the small diameter tubing removed) or an aerosol face mask attached to the circle system by large diameter extension tubing (Figure 2). This arrangement keeps the system pressure low and permits high gas flow at any FiO_2 . The high flow rate helps disburse the exhaled gas and minimizes re-breathing, and a low FiO_2 avoids oxygen trapping. When using the circuit in this fashion to provide an air: oxygen mixture, the APL must be closed in order to prevent the fresh gas from shunting to the scavange system.

When possible, room air is preferable for minimizing on-patient fires; however, this device should allow titration of FiO_2 to the lowest possible concentration when supplemental oxygen is required.

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Figure 1: Regular Oxygen Mask Attached to Circle System Causes Too High Resistance.

With the narrow diameter tubing connecting the oxygen mask to the anesthesia circuit, flow resistance creates a pressure gradient high enough to activate the continuing pressure alarm. Note the distended bag (see red arrow). Opening the APL would relieve this pressure, but then most of the fresh gas would go directly to the scavange system.



Figure 2: Aerosol Oxygen Mask (or regular oxygen face mask with thin diameter tubing removed) Attached to Circle System.

The large diameter tubing from extension tubing connects the aerosol face mask (or a regular oxygen face mask with the thin diameter tubing removed—see red circles) to the anesthesia circuit and permits a low pressure gradient of the air/oxygen mixture to the mask, avoiding the continuing pressure alarm (note the relaxed bag—see red arrow). The FiO_2 can be set at any desired value; the current setting would deliver approximately 29% oxygen.

**Check out the
Virtual Anesthesia
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APSF Anesthesia Machine
Workbook
at www.anest.ufl.edu/vam**

ISMP Survey Reveals Errors

"Drug Shortages," From Page 8

dilemma, there has been a continuing potential threat to patient safety. In a 2010 survey conducted by the Institute for Safe Medication Practices, 1 in 4 respondents reported their facility experienced errors due to a drug shortage. Examples of anesthetic drug errors that were reported to the Institute for Safe Medication Practices were:

- Intraoperative awareness when a patient was given too little propofol based on weight in an attempt to conserve supplies
- Dexmedetomidine concentration was misprogrammed in a pump causing a 20-fold overdose for 5 hrs
- Provider unfamiliar with dexmedetomidine; dosed drug in mcg/kg/minute rather than mcg/kg/hour
- Infused rocuronium at the rate for another neuromuscular blocking agent
- Patient received wrong dose of succinylcholine after an alternative concentration was substituted.⁵

Drug shortages have been a significant problem over the past decade. The shortage of numerous drugs used in anesthesia has not only been the unavailability of the medication but the number of critical medications amid the drug shortages, long duration of many of the shortages (average time 286 days), and the multiple times throughout the year the shortage reoccurs.^{12,13} For further information on drug shortages see the FDA website at: www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm and the American Society of Health-System Pharmacists at: <http://www.ashp.org/DrugShortages/Current/>

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Information Increases Awareness

"New Anticoagulants," From Page 9

However, for anesthesiologists, these drugs are often under-recognized as potential hazards during urgent operations and procedures such as regional anesthesia. In particular, patients are at high risk of developing epidural hematoma and neurologic complications during neuraxial anesthesia. Becoming familiar with the names, mechanism of action, and predicted half-life of these drugs is critical to safe anesthesia practice.

This information is intended only to increase awareness about the new anticoagulation medications appearing on the market and not to serve as peer-reviewed recommendations for patient care. Refer to the American Society of Regional Anesthesia guidelines on anticoagulation for more comprehensive consensus statements regarding patient management.

Dr. Gupta is Assistant Professor and Associate Director of Adult Acute Pain Service Vanderbilt University, Nashville, TN

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Vasoplegic Syndrome and Renin-Angiotensin System Antagonists

by *Torin Shear, MD, and Steven Greenberg, MD*

Unexpected refractory hypotension under general anesthesia is an increasingly recognized perioperative issue. One cause for this type of hypotension is vasoplegic syndrome (VS). It is most commonly seen during cardiac surgery, but can occur during any anesthetic. It is characterized by severe hypotension refractory to catecholamine therapy in the absence of other identifiable causes for hypotension. While there is no standardized definition for VS, some researchers have defined it as a mean arterial pressure <50mmHg with a cardiac index >2.5 L/min x m² and a low systemic vascular resistance despite adrenergic vasopressor administration.¹ The incidence of VS in cardiac surgical patients is 8% to 10 %, but may increase to upwards of 50% of patients taking renin-angiotensin system (RAS) antagonists.² In cardiac surgical patients with persistent hypotension into the postoperative period, the associated mortality approaches 25%.³ While RAS antagonists and their causal association with VS will be the focus of this review, many other risk factors exist. They include intravenous heparin, beta-blockers, calcium channel blockers, protamine use, myocardial dysfunction, diabetes mellitus, heart transplant, a higher added EuroSCORE, presence of pre-cardiopulmonary bypass (CPB) hemodynamic instability, valvular and heart failure surgery, increased duration of CPB, or ventricular assist device insertion.^{4,5} Some authors suggest holding RAS antagonists preoperatively in order to prevent VS. A lack of evidence has precluded clear guidelines surrounding the perioperative use of RAS antagonists thus far. To recognize and treat VS, a thorough understanding of the proposed mechanisms of this syndrome and current state of the science is needed to guide best-practice decisions.

Under normal physiologic circumstances, blood pressure is maintained via three separate but redundant systems: the sympathetic system, the renin-angiotensin system and the vasopressinergic system. Most anesthetic drugs reduce the influence of the sympathetic system on cardiovascular tone. Therefore, under general anesthesia there is believed to be an increased reliance on the RAS and the vasopressinergic system to maintain blood pressure.⁶ RAS antagonists such as angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) block the RAS response to hypotension. Therefore, patients taking these agents have an increased risk of refractory hypotension under general anesthesia.² Other proposed mechanisms for developing VS include: cytokine and nitric oxide-mediated smooth muscle relaxation, catecholamine receptor down regulation, cell hyperpolarization, and endothelial injury.⁴

ACEIs and ARBs are commonly utilized in patients with hypertension, congestive heart failure and diabetic neuropathy. ACEIs prevent the

conversion of angiotensin I (ATI) to angiotensin II (ATII), which results in lower arterial resistance, increased vascular capacitance, increased cardiac output, and stroke work. ACEI promote natriuresis and a reduction in left ventricular hypertrophy. ARBs act along the same RAS pathway. These agents block the ATII receptor for a more complete RAS blockade. Multiple drugs exist within both classes, each with different pharmacokinetic properties that may alter the timing of RAS recovery after cessation of the drug. Observational and randomized trials have demonstrated that stopping the RAS antagonist the day before surgery may attenuate VS.⁶ However, when longer acting agents are stopped 24 hours prior to surgery, RAS antagonism may still persist into the operative period.⁶

The treatment of VS can be challenging. Endogenous release of vasopressin (AVP) occurs to compensate for the blockage of both the RAS and the sympathetic nervous system, but this may not resolve the hypotension. When conventional therapies such as: decreasing the anesthetic agent, volume expansion, phenylephrine, ephedrine, norepinephrine, and epinephrine are not effective, exogenous vasopressin may improve hypotension. To date, at least 5 clinical trials have demonstrated that patients on chronic ACEI/ARB undergoing general anesthesia, respond to exogenous vasopressin derivatives with an increase in blood pressure and fewer hypotensive episodes.^{6,7} Typically, a 0.5-1 unit bolus of AVP is administered to achieve a rise in mean arterial pressure.⁴ The subsequent recommended infusion dose is 0.03U/min for AVP and 1-2 mcg/kg/h for terlipressin. Caution should be used as V1 agonists have been associated with the following deleterious effects: reduction in cardiac output and systemic oxygen delivery, decreased platelet count, increased serum aminotransferases and bilirubin, hyponatremia, increased pulmonary vascular resistance, decrease in renal blood flow, increase in renal oxygen consumption, and splanchnic vasoconstriction. Ischemic skin necrosis has been reported after peripheral intravenous administration through an infiltrated intravenous line.⁸

Methylene blue (MB) or tetramethylthionine chloride is a well described alternative treatment for VS.¹ It is believed to interfere with the nitric oxide (NO)-cyclic guanylate monophosphate (cGMP) pathway, inhibiting its vasorelaxant effect on smooth muscle.⁴ Case series and reports have suggested that MB may be effective in raising mean arterial pressure while minimizing the use of vasopressors in a variety of patient populations with VS such as; patients with severe burns, septic shock, liver transplant, and pheochromocytoma surgery.⁴ However, the literature is most robust regarding the use of MB in patients undergoing cardiac surgery. Studies involving cardiac surgical patients suggest that MB treatment for

patients with VS may reduce morbidity and mortality.⁵ It has also been suggested that the early use (preoperative use in patients at risk for VS) of MB in patients undergoing coronary artery bypass grafting may reduce the incidence of VS.^{5,9} A bolus dose of 1-2mg/kg over 10-20 minutes followed by an infusion of 0.25mg/kg/hr for 48-72 hours is typically utilized in clinical practice and trials (with a maximum dose of 7 mg/kg).¹⁰ Side effects include cardiac arrhythmias (transient), coronary vasoconstriction, increased pulmonary vascular resistance, decreased cardiac output, and decreased renal and mesenteric blood flow.¹ Both pulse and cerebral oximeter readings may not be reliable during MB administration due to wavelength interference.^{11,12} The use of MB is absolutely contraindicated in patients with severe renal impairment because it is primarily eliminated by the kidney.¹³ It may also cause methemoglobinemia and hemolysis.¹³ At high doses, neurotoxicity may occur secondary to the generation of oxygen free radicals. Neurologic dysfunction may be more severe in patients receiving serotonergic agents such as: tramadol, ethanol, antidepressants, dopamine agonists and linezolid. Recommended doses for VS ranging from 1-3 mg/kg do not typically cause neurologic dysfunction.¹⁴ However, recent reports suggest that MB in doses even ≤ 1mg/kg in patients taking serotonin reuptake inhibitors (SSRIs) may lead to serotonin toxicity due to its monoamine oxidase (MAO) inhibitor property.¹⁵ Further studies are warranted to investigate if other patient populations are susceptible to MB induced neurotoxicity at these lower doses.

While both vasopressin and MB are effective second line therapies for VS, many questions still exist concerning how best to manage this syndrome perioperatively. Further investigation into the proper timing and dose of V1 agonists and MB is needed.

With regards to prevention, retrospective trials have suggested stopping ACEIs/ARBs in advance of anesthesia to reduce the incidence of hypotension.¹⁶ A recent large retrospective trial from the Cleveland Clinic suggested that the preoperative use of ACEIs (withholding ACEIs on the morning of surgery only) was not associated with an increase in perioperative vasopressor use, in-hospital complications or 30-day mortality.¹⁷ However, questions still remain regarding the timing for discontinuing these medications.¹⁸ Given the pharmacologic differences of each ACEI/ARB, the appropriate timing for cessation is likely to be different for each medication. In addition, research to determine the possible harm of stopping these medications perioperatively is lacking. Lastly, outcomes regarding placing patients on appropriate alternative agents for perioperative blood pressure control should be investigated.

See "Vasoplegic Syndrome," Next Page

Vasoplegic Syndrome References Provided

"Vasoplegic Syndrome," From Preceding Page

While many questions remain, it is clear that refractory hypotension under general anesthesia is a recognized problem correlating with the increased use of RAS antagonists. It may be reasonable to discontinue these medications perioperatively, but evidence to support a "best-practice" guideline is lacking. Should VS occur, conventional therapies remain first line with vasopressin/terlipressin and methylene blue as reasonable second line options. Further research is needed to help elucidate the definition, causes, and best prevention and treatment strategies for vasoplegic syndrome.

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See "Vasoplegic Syndrome," Page 23

Many Respondents Report Policy Changes

"Fire Video," From Page 2

Figure 5

Has the APSF fire safety video resulted in a policy change on how supplemental oxygen is administered to patients "at risk" for an operating room fire (check all that apply)?

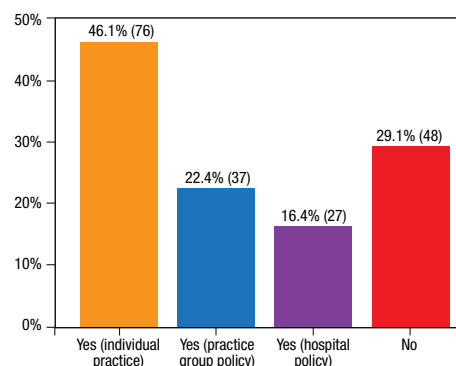


Figure 6

During your years in anesthesia (training and practice) how many operating room fires are you personally aware of in your institution/facility?

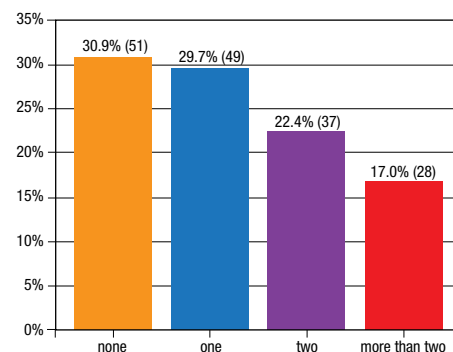
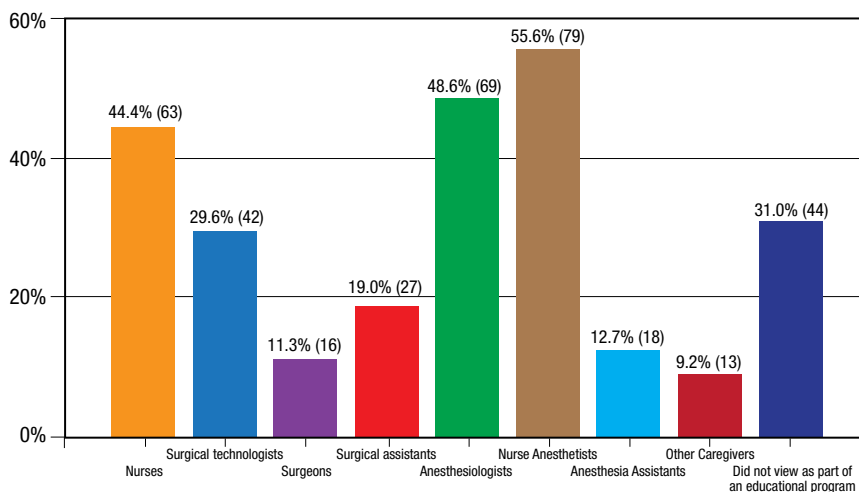


Figure 7

If you viewed the APSF fire safety video as part of a departmental or institutional educational program, who else participated in the educational program (check all that apply)?



The majority of survey respondents indicated the APSF fire safety video resulted in a policy change (individual, group, hospital) on how supplemental oxygen was administered to at risk patients (Figure 5).

Additional survey responses revealed that 89.5% of the 167 respondents had been in clinical practice more than 10 years and 69.1% indicated they were aware of one or more operating room fires (17% more than two fires) in their institution/facility (Figure 6).

Survey responses indicated the APSF fire safety video was most likely to be viewed as part of a departmental or institutional educational program that included multiple categories of health care professionals (Figure 7).

Overall, 65% of the respondents rated the APSF fire safety video as "extremely valuable" in their practice, 31.9% rated the video as "valuable," and 2.5% rated the video as "neutral" in value. Only 6.2% of respondents viewed the lack of CME credit for the APSF fire safety video as detracting from its educational value.

In this era of information overload, APSF believes that educational videos (focus oriented and succinct) offer an opportunity to reach the appropriate audience and change practice. Although surveys cannot be characterized as meeting standards of scientific rigor and may be subject to flaws in their interpretation, these survey results suggest the APSF fire safety video did change practice (administration of supplemental oxygen and management of the patient's upper airway) among those anesthesia professionals responding to the survey.

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*The complete survey and responses can be requested from Dr. Stoelting (stoelting@apsf.org).

Writing Standards to Improve Safety:

How ASA's Involvement Helped Make Dramatic Changes

by Jan Ehrenwerth, MD, and Steven Barker, MD, PhD

For over 50 years a small group of ASA liaisons have represented anesthesiologists and our patients at various national and international standards-making organizations. In the United States, a standard is usually a document arrived at by a consensus of interested individuals and/or organizations, and approved by a recognized body. "In reality, a standard is an agreed restriction for a common good and a shared benefit" (personal communication, Michael Jaffe).

Many organizations and individuals participate in the process. These include professional organizations, manufacturers, and interested individuals. The overall goal of codes and standards is to improve safety. However, some groups may be primarily concerned with cost savings or marketability of their products.

The National Fire Protection Association (NFPA) is one organization that publishes over 300 codes and standards. The ones that are of interest to the health care industry include NFPA 1—the National Fire Code; NFPA 50—the Standard for Bulk Oxygen at Consumer Sites; NFPA 55—Compressed Gas and Cryogenic Fluids Code; NFPA 70—The National Electric Code; NFPA 99—The Health Care Facilities Code;¹ and NFPA 101—The Life Safety Code.

Normally, each of the NFPA codes is eligible for review and revision every 3 years. The 2012 edition of NFPA-99, which is the main document of interest to anesthesiologists, was rewritten completely. However, this process took 7 years. There are many significant changes to NFPA-99, many of which were a direct result of the participation of ASA's liaisons in the process.

The process to change a code or standard begins with the submission of a proposal. These proposals are then reviewed by a technical committee (TC) that has expertise in that area. ASA has representation on the technical committees on piping systems, electrical systems, and medical equipment. Once the TC votes on the proposal, it is then open to public comment. After the comment period closes, the TC will meet again to consider the comments. If the proposal receives favorable action from the TC it then is up for vote at the general assembly. After final approval, it will then be an addition or change to the standard. Clearly, it is essential to participate at the TC meetings, in order to have changes adopted.

The 2012 edition of NFPA-99 has many significant changes. We will discuss some of the important changes that are of interest to anesthesiologists. The latest edition has transitioned from a standard to a code. This means that it is more likely to be adopted by the local authorities and jurisdictions as a regulatory code. Another significant change is that the document uses a risk-based, rather than an occupancy-based model. Previous editions classified



buildings and requirements based mainly on size. Thus, a large, 500-bed acute care hospital had many more requirements for systems like back-up power and oxygen, than a small 2 or 3 operating room Surgicenter. In the new code, the risk to the patient of a failure of a system will determine what systems are needed. Therefore, if that small Surgicenter is doing general anesthesia, then they will have to have the same emergency backup systems as a large hospital.

In the past an anesthetizing location was defined only as a place where general anesthesia was given. That would not apply to the modern practice of anesthesia. We now have the ASA's definitions of "levels of sedation" written into the code. This will directly impact how the code is applied, and whether or not a treatment area will be considered an anesthetizing location.

In previous editions, the code only applied to new or remodeled facilities. An important change to the 2012 edition, are provisions that apply to existing facilities. This includes the maintenance and testing of certain systems.

Medical Gas Systems

There are new requirements for the maintenance and testing of the medical gas and vacuum system. In addition, the personnel maintaining these systems must be qualified to perform these operations. These qualifications are defined in the code, and the aim is to ensure that individuals working on medical gas pipelines are properly trained and competent to do the work.

The code now allows medical gas and vacuum systems to be used only in areas where they will be under the direction of a licensed medical professional. Section 5.1.3.5.2 states that "medical gases shall be used only for the following purposes:

1. Direct respiration by patients
2. Clinical application of the gas to a patient, such as the use of an insufflator to inject carbon dioxide into patient body cavities during laparoscopic surgery

See "Standards," Next Page

ASA Liaisons Writing Standards

"Standards," From Preceding Page

3. Medical device applications directly related to respiration
4. Power for medical devices used directly on patients
5. Calibration of medical devices intended for (1) through (4)"

Clearly, using medical gases for purposes such as drying endoscopes is not an approved application.

A proposal was approved by the TC on medical equipment, whereby manufacturers of ozone sterilizing equipment could tap directly into the patient oxygen pipeline. We felt strongly that the oxygen pipeline should be used only for the purposes stated above. Drs. Ehrenwerth and Barker spoke strongly against this proposal at the general assembly, and subsequently it was defeated.

The code was reorganized to remove the bulk oxygen central supply requirements from NFP-99 to NFPA-55 (Compressed Gases and Cryogenic Fluid Code). A new change allows the pipeline supplying the bulk oxygen, from a source outside the building, to be split inside the building. This would allow the 2 sections to operate at different pressures. Thus, one could be for normal patient use, and the other could be at a higher pressure for a hyperbaric pipeline. Previously, separate pipelines would be needed, from the source. This change has significant cost-saving possibilities.

The requirements for medical air compressors have also been tightened up. The requirements for air quality have been improved, and the location of the air intake for the compressor(s) is more stringent. For instance, the intake can not be located where motor vehicles are running and where exhaust gas may be drawn into the air compressor.

This edition of the code now allows hospitals to make their own medical air, by blending nitrogen and oxygen. This has potential cost savings over the purchase and maintenance of medical air compressors. Of course, these mixing systems would need to be monitored to assure that they are getting a correct 21% oxygen and 79% nitrogen mixture.

Several fires have been reported in systems where the surgical vacuum and waste anesthesia gas disposal (WAGD) systems have been combined. These fires occurred in systems that used oil lubricated vacuum pumps. The new codes require that if the institution is using oil-lubricated vacuum pumps, then the total concentration of oxidizers ($O_2 + N_2O$) shall be maintained at less than 23.6%. If this can not be achieved, then the institution must use pumps that utilize lubricants that are safe in high oxidizer environments.

In 1984, NFPA acknowledged the elimination of explosive agents from anesthetizing areas. Subsequently, the requirement for isolated power in operating rooms was made optional. An unpublished study by a large hospital consortium claimed that

isolated power was unnecessary and extremely costly to install and maintain. This was the impetus for many hospitals not installing isolated power in new or remodeled operating rooms. In the following years, ASA's liaisons made several unsuccessful attempts to reinstate isolated power. The rewriting of NFPA-99 presented an opportunity to revisit this important provision. The ASA and anesthesiologists all across the country felt that additional electrical safety measures were necessary in the hazardous environment of the modern operating room.

We introduced a proposal to change the code so that all new or remodeled operating rooms would default to being a wet procedure location. Hundreds of anesthesiologists submitted comments to support this proposal, and we were able to show that the cost estimates by the consortium were grossly overstated. Although the opposition was strong and well-organized, we were able to persevere. Therefore, the 2012 edition of the code states that all new or remodeled operating rooms will default to being a wet procedure location. That means that special electrical protection in the form of isolated power, or ground fault circuit interrupters (GFCIs), will have to be installed, unless the facility does a risk assessment to prove that certain ORs are **not** wet locations. This is indeed an epic victory for ASA and our patients. Other relevant changes include a requirement that all electrical/gas booms be inspected on a regular basis, and that a minimum of 18 electrical outlets be installed in a critical care area and 36 in an operating room (the previous requirement was 6!).

ASA, through its liaisons, can make significant changes to national codes and standards. However, this requires an in-depth understanding of the code making process for that organization, the ability to form alliances, and a long term commitment to working within that organization. During the past 7 years of developing the new NFPA-99 code, ASA representatives have been able to have a major input into the process, and thereby make significant changes that will improve the safety of operating room personnel and our patients.

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The author would like to thank Jonathan Willard and Michael Jaffe for supplying reference material for this article.

Dr. Ehrenwerth is Professor of Anesthesiology, Yale University School of Medicine, New Haven, CT, and Dr. Barker is Professor and Head, Department of Anesthesiology, University of Arizona College of Medicine, Tucson, AZ.

Improved Safety Requires Collaboration

"Postoperative Monitoring," From Page 4

comorbidity data, without the need for the user to provide additional input or set alarms and triggers.

Finally, we would like to emphasize the importance of strong collaboration between engineers, nurse, physicians, and technology providers to make patient surveillance work. All stakeholders must be engaged and work together to facilitate the establishment of a safer clinical environment.

Andreas H. Taenzer, MS, MD, is an Associate Professor of Anesthesiology and Pediatrics, and George T. Blike, MD, is Professor of Anesthesiology at The Geisel School of Medicine at Dartmouth, Dartmouth Hitchcock Medical Center. This article was an invited submission in followup to the APSF Consensus Conference on "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period."

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Letter to the Editor:

Kinked Inspiratory Limb of Coaxial Circuit Mimics Bronchospasm

A 68-year-old male was scheduled for a right knee arthroplasty after a previous distal femoral replacement became dislocated. Standard ASA monitors were placed and induction was performed with propofol and succinylcholine. The patient was successfully intubated with a Glidescope®, and the endotracheal tube was visualized entering the glottis. The endotracheal tube was connected to the anesthesia circuit and mechanical ventilation was initiated, but the patient rapidly became difficult to ventilate. The SpO₂ decreased to the 88-90% range with a positive end-tidal CO₂ tracing on the anesthesia monitor. Upon auscultation, bilateral breath sounds were audible, but significant wheezing was present. Heart rate and blood pressure were not significantly altered from preoperative values. With elevated peak airway pressures, bronchospasm was presumed and the patient was treated with nebulized albuterol as the anesthetic level was deepened. The airway was quickly inspected with a fiberoptic bronchoscope and no foreign bodies or mucous plugs were identified. The wheezing, difficult ventilation, and decreased oxygen saturations persisted. After exhausting the alternatives, the breathing circuit was exchanged for a new circuit and almost immediately, the patient became easier to ventilate, the wheezing ceased, and the oxygen saturations improved to 99%.

Upon close visual inspection of the equipment, a kink was noted in the inspiratory limb of the coaxial circuit, Figures 1-4. The kink allowed ventilation to occur against moderate resistance at higher than normal pressure, but it was not severe enough to completely occlude gas flow. The partial blockage not only slipped through the earlier equipment check, but it delayed the response to switching to an ambu bag as an alternate method of emergency ventilation. If the kink had caused complete obstruction, and total flow had been occluded, the circuit would likely have been suspected as the cause sooner, and an alternate method of ventilation sought. The circuit, in its damaged state, did not trigger any alarm during the automated anesthesia machine check-out of the Datex Ohmeda Aisys machine prior to the case start. After this incident, the breathing circuit involved was placed on 2 additional anesthesia machines, where it failed to trigger an alarm during the automated check-out process. In the pre-anesthetic visual inspection of the machine and equipment, it appeared to be a functional circuit.

Per hospital policy, a safety report was filed and both the manufacturer and the FDA were informed. The malfunction was later confirmed by the manufacturer of the breathing circuit. The problem was isolated to a faulty adaptor that prevented the full rotation of the inner tube during assembly, and

instead, the tube folded on itself. The manufacturer has since implemented a 100% light-box inspection of each circuit after final assembly.

Kinking of the inner tubing of a Bain coaxial circuit has been previously reported.^{1,2} Several interventions and techniques have been developed to minimize its occurrence. In this case, the inner tubing of the coaxial cable kinked despite the fact that it was corrugated. Several maneuvers have been described for ensuring the patency of the inspiratory limb,³⁻⁵ but none of them are fool-proof. Additionally, if not performed carefully, they have the potential to damage the circuit or the machine.⁶

This case has also demonstrated to us the role that cognitive errors play in critical scenarios.⁷ We believe that availability bias (choosing a diagnosis because it is frequently encountered) and representativeness (failure to consider circuit malfunction, because circuit malfunction typically presents with complete obstruction) played a role in the delayed diagnosis of the circuit as the cause of the difficulty ventilating this patient. Since circuit malfunctions are a rare event and the machine passed the automated safety check at the start of the case, we did not consider a malfunctioning breathing circuit to be high on our list of differential diagnoses. This was combined with the fact that only a partial occlusion was present, which did not trigger an immediate "popoff" during inspiration since some flow occurred through the circuit. This case serves as a reminder that even with advancing automation of the anesthesia machine safety check-out, nothing can replace a careful and thorough visual inspection of the equipment before each case.

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Tariq Chaudhry, MD
Moffitt Cancer Center
Tampa, Florida



Figure 1



Figure 2



Figure 3



Figure 4

Figures 1-4 show 4 different views of the kinked circuit causing the obstruction.

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Editorial Reply:

Functional Test of the Ventilation and Breathing Circuits Will Detect Kinked Circuit

by A. William Paulsen, MMSc, PhD, CCE, AAC

The minimum anesthesia machine checkout between each case should include a functional test of the ventilation and breathing circuits. The automated machine checkout procedure really only looks for leaks and possibly measures breathing circuit compliance. To perform a functional test remove the breathing bag from the bag arm and place it on the breathing circuit elbow where the mask or endotracheal tube is usually connected. Switch to ventilator mode and fill the bellows with oxygen. While the breathing bag is being mechanically ventilated, you will see if the machine is able to deliver positive pressure ventilation to the bag. Comparing the set tidal volume to the measured exhaled tidal volume after 7 or more breaths would have identified the problem in this case before the machine was used with the patient. The exhaled volume being much less than the volume set to be delivered.

This functional test would also identify a leak in the breathing circuit in some machines or a leak in the breathing circuit plus low pressure side of the machine in others. As the ventilator bellows descend and then rise, if they continue to rise to lower and lower levels the breathing circuit is losing more gas than is entering from the common gas outlet. In the Aisys machine, if the waste anesthetic gas disposal system is not functioning properly and total gas flow is set to 1 or more liters/minute the positive end expiratory pressure will rise to displayed 12 cmH₂O or greater. Depending upon where the machine measures and displays pressure, it may have been possible to observe a severe obstruction by looking at the inspiratory pressure or the inspiratory pressure waveform.

The pressure waveform in the volume control mode with inspiratory pause is a great way to separate airway resistance from alveolar pressure as pictured below.

Normally the peak pressure is only a little higher than alveolar pressure. However, in Figure 1 there is significantly increased resistance in the breathing circuit and it appears as a large spike in the pressure. The peak pressure is a function of airway resistance times flow, indicating how a change in resistance can be observed from the waveform if the inspiratory flow remains constant. The airway flow can be increased by changing the I:E ratio from 1:1 to 1 to 10 for example.

When the inspiratory pressure is maintained constant (inspiratory pause) there is no more flow of gas into the lungs and the volume remains constant. This means that the airway pressure is equal to the alveolar pressure. The alveolar pressure is then related to the volume in the lungs divided by the static compliance of the lungs. If the tidal volume remains constant, then changes in alveolar pressure are related to changes in pulmonary compliance. A functional check of the breathing circuit should be performed before the start of every case.

Dr. Paulsen is Chair of the APSF Committee on Technology and Professor of Medical Sciences Frank Netter School of Medicine Quinnipiac University, Hamden, CT.

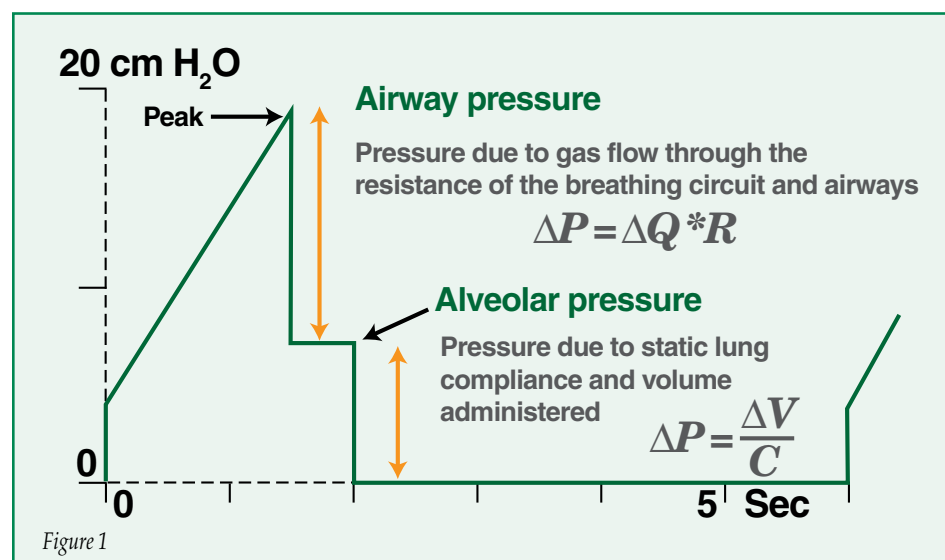


Figure 1

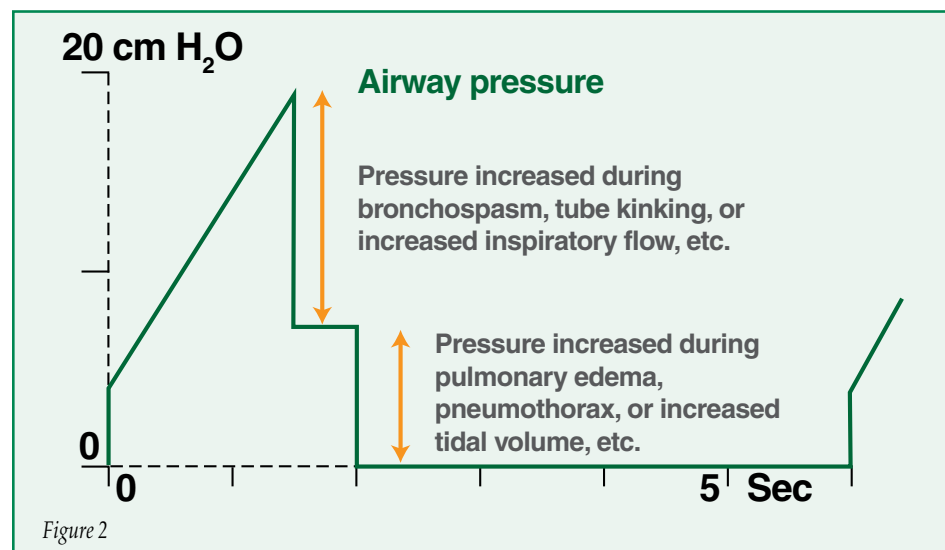


Figure 2

Figures 1 & 2: Data Gained from Pressure Waveform during Inspiratory Pause

Vasoplegic Syndrome References Provided

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Patient Safety Through Education: The Human Resources for Health in Rwanda Program

Anesthesiologists in Rwanda are truly one-in-a-million. There are currently 11 anesthesiologists in Rwanda to support a population of 11 million citizens. Most anesthetics are delivered by anesthesia technicians possessing little more education than high school equivalency. Minimum perioperative standards, such as the availability of oxygen and basic monitoring equipment, do not exist. Newly minted physicians have little opportunity to pursue residency training within their own country since residency training slots are limited by lack of teaching faculty. Therefore, many recent medical school graduates seek training overseas. They often find fulfilling careers and personal lives outside their country, making their return improbable (external brain drain). Those who do return find they may not be able to practice the medicine for which they were trained. Remarkably, the majority of recent medical school graduates in Rwanda leave clinical medicine entirely to join Non-Governmental Organizations operating in the country (internal brain drain).

It will be no surprise that this lack of anesthesiologists and suitable equipment translates into a greatly increased perioperative risk for patients. Indeed, perioperative mortality hovers around 5%, even at Rwanda's university hospital.

The Rwandan government has developed a bold plan to address these patient safety issues by increasing the capacity of residency training programs, growing the numbers of practicing physicians, and creating a high quality, sustainable health care system. This Human Resources for Health (HRH) in Rwanda program is a 7-year medical education initiative encompassing anesthesia, surgery, obstetrics & gynecology, pediatrics, internal medicine, and family practice. Concurrent programs will address the shortage of nurses and deficiencies in equipment and supplies. Funded by a large grant from the US government, the Rwandan Ministry of Health has contracted with 9 US medical schools to provide the faculty to train Rwandan residents and to mentor Rwandan faculty to become educators. The Clinton Health Access Initiative is providing organizational support to this effort. US candidates will be vetted through, and receive temporary appointments at, the US schools in order to participate. In August of 2012, the US schools will begin sending more than 50 physicians in the above specialties for long-term (1-year) assignments. We expect to send 4 anesthesiologists per year to Rwanda. At a later date short-term (1-3 month) assignments for sub-specialists will also be available. After 7 years, US faculty will be phased out, as Rwandan medical faculty assumes full responsibility for the residency training programs.

This is a fabulous opportunity for US anesthesiologists to participate in a program that will improve perioperative patient safety, define anesthetic practice parameters, and determine anesthetic training objectives from the ground up. In collaboration with our Rwandan colleagues, participants will determine perioperative monitoring and practice standards, define relationships with other departments such as Surgery and Emergency Medicine, and develop a curriculum for the training of anesthesiology residents. The Canadian Anesthesiologists' Society International Education Foundation, in conjunction with the American Society of Anesthesiologists' Global Humanitarian Outreach program, has been working in Rwanda since 2006, supporting anesthesia residency training. The HRH program will provide the necessary resources to help transform this effort into a thriving, self-sustainable program.

When non-Rwandans hear the word "Rwanda," what immediately comes to mind is post-colonial, ethnic tension and the horrific genocide of 1994. When Rwandans think about their country today they think about post-genocide healing and tremendous hope for the future. Unity and reconciliation efforts in Rwanda (based on the South African "truth and reconciliation" model) have successfully moved the population beyond ethnic strife. Rwanda today

is a very safe place to live and work. The US Department of State has no travel restrictions in place, and according to the anti-corruption watchdog, Transparency International, the government of Rwanda is among the least corrupt in all of Africa. International aid dollars are pouring in from all over the world. Rwanda's future is indeed bright. How lucky we are to have the opportunity to be a part of this monumental effort!

For more information about participation in the HRH program, please contact us at anesthesia@rwandahrh.com.

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Relatives of patients on the campus of the Health Center of the University of Kigali, Rwanda.

Q&A

Should Inhalational Anesthesia Capability Be Required as Backup for TIVA?

Q Dear Q&A,

From a patient safety perspective, do you consider it necessary to be able to switch to vaporizer-based inhalational anesthesia during TIVA, e.g., in case of an infusion line disconnect or would it be sufficient with anesthesia equipment for performing TIVA only in, e.g., an ambulatory anesthesia setting?

Stefan Strömberg
Gidac
Sigtuna, Sweden

A Dear Reader,

1. If the primary concern is a patient who loses his/her IV and for whatever reason another one cannot be started in time before the patient awakens, the choice is an anesthesia machine with a vaporizer (e.g., sevoflurane), especially if the patient has received neuromuscular blocking agents.
2. If the IV is lost (pulled out or infiltrated) and another can be started easily and quickly, there is no need for a vaporizer.
3. If the pump fails it should be easy to administer agent with a syringe while another working pump is setup and turned on.
4. If the pump tubing fails, again a syringe could be connected to the IV cannula and used to bolus the agent until the tubing can be replaced and the pump restarted.

Numerous questions to the Committee on Technology are individually and quickly answered each quarter by knowledgeable committee members. Many of those responses would be of value to the general readership, but are not suitable for the Dear SIRS column. Therefore, we have created this simple column to address the needs of our readership.

This is the safety issue (not the vaporizer): In all cases there should be a correctly sized self-inflating breathing bag with appropriate sizes of masks and an oxygen tank to which it can be connected, immediately available in the room with the patient.

Under ideal circumstances an anesthesia machine with ASA monitoring should be available everywhere an anesthetist or anesthesiologist will deliver anesthesia care to the patient.

If this is an area where non-anesthesia personnel will be sedating patients, the self-inflating bag and oxygen tank must be present. An anesthesia machine and vaporizer will be of little value.

The APSF Committee on Technology

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

APSF Executive Committee Invites Collaboration

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

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Steven R. Sanford, JD.....Preferred Physicians
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Andrew Levi.....Spacelabs

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Susan K. Palmer, MD.....The Doctors Company

William Fox.....WelchAllyn

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Letter to the Editor

Reader Raises Two Propofol Concerns

Condensation was noted on the stopper of vials of propofol and inside the flip top cap which raised concerns about the drug's potential sterility (Figures 1 and 2). Attempts to culture the fluid were unsuccessful due to the rapid evaporation and minimal amount of condensation. Subsequently, we actively looked for evidence of the condensate; however, it was only present in a small minority of cases.

We contacted APP Pharmaceuticals (Schaumburg, IL), which markets the sulfite-free generic propofol and Diprivan®. The manufacturer responded that condensation occurs secondary to the auto-sterilization process and poses no risk to the patient. During terminal sterilization, the vials are subjected to circulating water for injection. As a result, water condensation may be present between the vial's silicone stopper and the flip cap. The manufacturer further stated that the water evaporates when the flip cap is removed and that this condensate has no impact on the quality or integrity of the product.¹ The package inserts for both propofol and Diprivan® recommend that strict aseptic techniques be used in preparing and administering the agents and that vials be disinfected

with 70% isopropyl alcohol prior to administration.^{2,3} However, the package inserts of cisatracurium (Nimbex®), succinylcholine chloride (Anectine®), and etomidate (Amidate™) carry no similar recommendation to swab the stopper of the vials (Table 1).

In addition, Exparel™ a new white aqueous suspension of multivesicular liposomes containing bupivacaine may look similar to propofol (Figure 3) also carries no similar recommendation.⁴ The recommendation to swab the vials of propofol and Diprivan® may be due to its formulation in a white, oil-in-water emulsion. Of note, both propofol and Diprivan® also contain disodium edetate (0.005%) to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination.

Moreover, it is difficult to determine what percent of single dose vials are being swabbed during routine practice of anesthesia. Thus for patient safety, we believe that providers should routinely swab propofol and Diprivan® vials prior to administering these agents and be aware of another drug that may look similar.

Table 1. Comparison of Medications

IV Medication	Disinfection with 70% Isopropyl Alcohol
Propofol (APP)	Recommended
Propofol (Diprivan® AstraZeneca)	Recommended
Etomidate (Amidate™ Hospira)	No Instruction
Rocuronium (Sandoz)	No Instruction
Cisatracurium (Nimbex® Abbott)	No Instruction
Succinylcholine chloride (Anectine® Sandoz)	No Instruction
Bupivacaine liposome (Exparel™ Pacira)	No Instruction

References

1. Propofol Injectable Emulsion, USP Condensation. Letter from APP.
2. Propofol Injectable Emulsion, USP. Package Insert.
3. Diprivan Injectable Emulsion, USP. Package Insert.
4. Exparel (Bupivacaine Liposome Injectable Suspension), USP. Package Insert.

Elizabeth Rebello, MD

Joel Berger, CRNA

Spencer Kee, MD

The University of Texas MD Anderson Cancer Center
Houston, TX



Figure 1



Figure 2



Figure 3

Figures 1 and 2. Liquid condensate appears on the stopper after flip cap is removed.

APSF Sponsored Conference on Wednesday, September 12, 2012



Perioperative Visual Loss—Who is at risk? What should we tell patients preoperatively? And, how should we manage their intraoperative care?

Royal Palms Resort and Spa, Phoenix, AZ

APSF believes that increased awareness and understanding of risk factors associated with perioperative visual loss (POVL) is a timely patient safety topic. The goals of this 1-day multidisciplinary conference are to assure that current management reflects evolving information and understanding of "best practices" for patients at risk for POVL. Specific questions that will be addressed include

- Shared decision making (patient, surgeon, anesthesia professional)
- Who is "at risk"
- Informed consent (timing and by whom?)
- How is anesthetic and surgical management influenced?

Contact Robert K. Stoelting, MD, at stoelting@apsf.org for registration information.

Awareness of LAST is Critical; Checklist Improves Treatment

"LAST Checklist," From Page 14

exposed delay in prompt notification of cardiopulmonary bypass teams. Finally, the Virginia Mason simulation exercise clearly unmasked the trainees' reluctance (and presumably that of other providers) to follow the checklist. This hesitancy of health care providers to embrace checklist use has been well documented. The study clearly demonstrated that failure to fully use the checklist resulted in fewer correct treatment actions, not only as they relate to suboptimal management of cardiac arrest, but also to mental failure in accurately recalling lipid emulsion dosing parameters.

The Anesthesia Patient Safety Foundation recently funded a project at the University of Illinois College of Medicine to produce an educational "tool-kit" for distribution to academic anesthesia departments on the topic of LAST. This instructional program is comprised of a DVD that includes lectures, sample simulations, and a movie along with current supporting documents such as the ASRA Checklist.

Local anesthetic systemic toxicity continues to be a potentially devastating complication of anesthesia practice. The ASRA practice advisory and its associated checklist help us to better understand the prevention and diagnosis of LAST, and are particularly useful for prompting our brains at a time of intense stress when our patient unexpectedly shows signs of severe toxicity. As experts in the use of local anesthetics, it is important that we take every opportunity to increase the awareness of LAST among non-anesthesia providers, e.g., surgeons or emergency physicians, who might use local anesthetics but are unaware of their potential risks. Other specialists are unlikely to know that there are currently accepted methods for managing acute LAST, including an effective antidote. It is our job to inform them.

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Professor of Anesthesiology
University of Illinois; Jesse Brown VA Medical Center
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1. Neal JM, Bernardis CM, Butterworth JF, et al. ASRA practice advisory on local anesthetic systemic toxicity. *Reg Anesth Pain Med* 2010;35:152-161.
2. Di Gregorio G, Neal JM, Rosenquist RW, Weinberg GL. Clinical presentation of local anesthetic systemic toxicity: A review of published cases, 1979-2009. *Reg Anesth Pain Med* 2010;35:181-187.
3. Neal JM, Mulroy MF, Weinberg GL. American Society of Regional Anesthesia and Pain Medicine checklist for managing local anesthetic systemic toxicity: 2012 version. *Reg Anesth Pain Med* 2012;37:16-18.
4. Neal JM, Hsiung RL, Mulroy MF, Halpern BB, Dragnich AD, Slee AE. ASRA checklist improves trainee performance during a simulated episode of local anesthetic systemic toxicity. *Reg Anesth Pain Med* 2012;37:8-15.

Letter to the Editor

Potential Hazards Created by Non-Standard Stopcocks

To the Editor:

Standardization of the look and feel of supplies and equipment plays an important role in achieving a safe environment for patients. A supply substitution in our OR resulted in the inventory placement of a stopcock which has a significantly different tactile and visual appearance when the side port is closed. This difference led to a period of delayed therapy when a medication infusion was inserted into the side port of a stopcock which was thought to be open, but was closed. The infusion pump occlusion alarm

sounded and visual inspection of the fluid path did not initially reveal the point of occlusion. Only after additional troubleshooting was the closed stopcock identified as the source of the occlusion. Careful examination of any new equipment, even equipment which appears to be similar to existing standards is necessary to ensure that the function matches what is expected.

Paul St. Jacques, MD
Nashville, TN

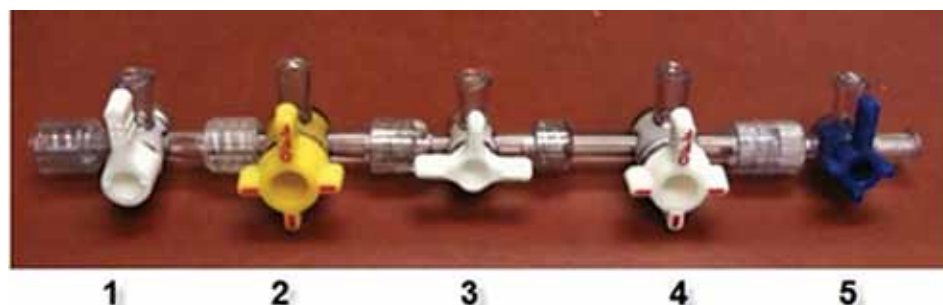


Figure 1. The stopcock labeled number 3 is open to the side port, whereas all of the others are closed to the side port. This potentially creates a dangerous situation as the appearance of a closed sidearm is 180° reversed from what is typically expected.

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*The Anesthesia Patient Safety Foundation (APSF)
announces the availability of
the 18 minute educational video:*

***Medication Safety
in the Operating Room:
Time for a New Paradigm***

View the DVD or request a complimentary copy on the
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In this issue:

**Postoperative Monitoring—
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