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### **Carbon Dioxide Absorbent Desiccation Safety Conference Convened by APSF**

by Michael A. Olympio, MD

There is increasing evidence that exposure of volatile anesthetics to desiccated carbon dioxide absorbents may result in exothermic reactions leading to fires in anesthetic breathing circuits and production of toxic products (e.g., carbon monoxide, compound A, methanol, formaldehyde). Although fires have only been reported in association with sevoflurane exposed to desiccated Baralyme<sup>®</sup> (Allied Healthcare/Chemetron, withdrawn from the market), there is significant evidence that potentially toxic products can be produced upon exposure of volatile anesthetics to other desiccated absorbents containing strong bases, particularly potassium and sodium hydroxide. In some cases this may lead to sub-clinical carbon monoxide exposure.

In view of these continued anesthesia patient safety concerns, the Anesthesia Patient Safety Foundation invited medical experts and industry representatives (manufacturers of carbon dioxide absorbents, anesthesia machines, and volatile anesthetics) to attend a conference entitled Carbon Dioxide Absorbent Desiccation: APSF Conference on Safety Considerations on April 27, 2005, in Chicago, IL. In addition to medical experts and industry representatives (Table 1), APSF invited several organizations, including the American Society of Anesthesiologists and the American Association of Nurse Anesthetists to send observers to the conference (Table 2). The conference was funded by the Anesthesia Patient Safety Foundation with the support of unrestricted educational grants from the 10 industry cosponsors.

The format of the conference included formal presentations by the 4 medical experts as well as presentations by representatives of industry. Following reports generated from small group break-out sessions there was general discussion among all attendees and development of a consensus statement to reflect the stated goal of the conference, which was *"to develop a consensus statement to share with anesthesia professionals on the use of carbon dioxide absorbents so as to reduce the risk of adverse interactions with volatile anesthetic drugs."* 



Left to right, Drs. Dorsch, Olympio, Kharasch, Woehlck, Stoelting, and Eger speak at the APSF Conference on Safety Considerations of Carbon Dioxide Absorbents on July 27, 2005, in Chicago, IL.

### Summary of Expert Medical and Industry Representative Presentations

Jerry A. Dorsch, MD, speaking on Anesthesia Machine Characteristics That Promote Absorbent Desiccation:

The retrograde flow of fresh gas through the absorber can desiccate the absorbent. This may be affected by a number of factors, including the design of the anesthesia breathing system, the presence or absence of the reservoir bag, whether the APL valve is open or closed, the relative resistance through the components of the breathing circuit, the fresh gas flow rate, I:E ratio, use of heat and moisture exchangers, and scavenger suction. With conventional breathing system design, removing the bag, opening the APL valve, and occluding the Y-piece all enhance retrograde flow and desiccation. The effects of these maneuvers in newer, more modern machines are variable, complex, and may have the opposite effect. Furthermore, we do not know of published data that describe the flow of gas under these various conditions. Unfortunately, the flow of gas in these breathing systems has not been well studied.

**Evan D. Kharasch, MD, PhD**, speaking on *Heat*, *Fire, and Smoke: Shining Light on the Issue of Carbon Dioxide Absorbents and Anesthetic Degradation:* 

The chemical breakdown to compound A can occur in moist, as well as desiccated absorbent, but the potential for highly exothermic reactions and

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### Boston University Video Honors Dr. Leroy Vandam

Dr. Leroy Vandam (1914-2004) was a great anesthesiologist, teacher, scientist, author, and artist. His career began in surgery and, under the leadership of Dr. Robert Dripps, became focused on anesthesiology. During his tenure at the Peter Bent Brigham Hospital (now known as Brigham and Women's), Dr. Vandam served as a mentor to Dr. Ellison C. (Jeep) Pierce, who became the founder of the Anesthesia Patient Safety Foundation. In fact, Dr. Vandam assigned Dr. Pierce the topic of "Anesthesia Accidents" to be given as a resident's lecture. Under the directorship of Dr. Rafael Ortega, Boston University Medical Center's Department of Anesthesiology, in conjunction with Anesthesia Associates of Massachuseetts, has honored Dr. Vandam's memory with a wonderful DVD entitled Leroy D. Vandam, MD: An Anesthesia Journey. This production illustrates numerous fascinating and historical aspects of Dr. Vandam's career, in the context of the evolution of anesthesia equipment. Safety ramifications of anesthesia equipment are obvious throughout this production. Dr. Vandam's own words and accounts of his experiences are a living history, and highlight his contributions throughout his incredible career. Copies of the DVD can be obtained by contacting the Anesthesia Department at Boston University Medical Center.

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



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## **Experts Review Absorbent Fundamentals**

### "Absorbents," From Page 25

fires with sevoflurane (liberating carbon monoxide, formaldehyde, and methanol) only occurs in desiccated absorbent and is enhanced by the type and quantity of strong base (KOH>NaOH). The renal effects of compound A formation under low flow sevoflurane anesthesia have been extensively evaluated in surgical patients and found to have no clinically significant adverse effects. The breakdown of desflurane, enflurane, and isoflurane (in descending order of magnitude) to carbon monoxide, requires desiccated absorbent and is also enhanced by strong base, and particularly Baralyme®. Baralyme® and Drägersorb® 800 produce more carbon monoxide than Drägersorb® 800 Plus (Dräger Medical, Inc.), Intersorb® and Spherasorb® (Intersurgical Ltd.), in descending order and with descending amounts of strong base. Clinical effects of carbon monoxide exposure have been described, but they may be concealed by post-anesthetic effects and cannot be detected by pulse oximetry. Fires have been reported in the USA with sevoflurane only and desiccated Baralyme®. However, cases of extreme heat associated with desiccated sodalime have also been reported in Europe. Dr. Kharasch strongly advocated the conversion to, and use of only carbon dioxide absorbents that do not contain strong base.

#### Harvey J. Woehlck, MD, speaking on Monitoring for Desiccation and Carbon Monoxide:

The production of carbon monoxide is greater with desiccated KOH absorbents than with desiccated NaOH absorbents, and is proportional to base concentration. By-products of sevoflurane include carbon monoxide, formaldehyde, methanol, methyl formate, dimethoxymethane, and perhaps hydrogen gas at high temperatures. [The relative ability of these by-products versus other combustible materials, such as plastics or gaskets, to serve as a fuel in a high heat oxygen-enriched environment is not known.] Desiccation of traditional absorbent and its production of carbon monoxide cannot be detected with routine anesthetic monitors. The blue-violet discoloration of traditional absorbents typically indicates exhaustion, and not desiccation. Rapid discoloration might also indicate degradation of the anesthetic agent. One absorbent (Amsorb® Plus, Armstrong Medical) does change color with desiccation, as desiccation is expected to occur with absorbent exhaustion. Diagnosing carbon monoxide toxicity is difficult with its indiscriminate and nondiagnostic symptoms of confusion, nausea, dyspnea, headaches, and dizziness that might also be symptoms of anesthetic emergence. Studies show that total cessation of carbon monoxide production cannot be achieved despite implementation of antidesiccation strategies. Monitoring of carbon monoxide gas in the circuit is currently possible with more sophisticated and more expensive detectors, and carboxyhemoglobin monitoring is available through co-oximetry, but is not routinely assessed. Indirect methods require particular gas analyzers that can detect trifluoromethane, an intermediate byproduct of isoflurane and desflurane. Volatile agents are not known to react with, or to produce compound A or carbon monoxide from Ca(OH)<sub>2</sub>, LiOH, or Ba(OH)<sub>2</sub>; however, theoretical chemistry provides for the potential reactivity of Ba(OH)<sub>2</sub>.

**Edmond I Eger, II, MD**, speaking on *Thoughts* on *Untoward Absorbent-Anesthetic Interactions:* 

The production of compound A and carbon monoxide arises from the action of the strong bases KOH and NaOH [and perhaps Ba(OH)<sub>2</sub>] on potent inhaled anesthetics. Compound A (implicated as a potential nephrotoxin) is produced in moist or desiccated absorbents with sevoflurane only. Carbon monoxide is only produced with desiccated absorbents, most with Baralyme® acting upon desflurane. Fires are known to occur only in the combination of sevoflurane and desiccated Baralyme®. Desiccated absorbents without KOH or Ba(OH)<sub>2</sub>, and with lesser amounts of NaOH, produce less heat and no fires, and dramatically less carbon monoxide or compound A. There is general recognition that all untoward events are rare and preventable at modest cost. Dr. Eger further stated that the production of toxic products can be eliminated through the use of absorbents containing only  $Ca(OH)_2$  with catalysts such as  $CaCl_2$  or  $CaSO_4$ .

### Industry Representative Comments

Industry representatives provided summary information on foundational topics. They appreciated the significance of a conference that would bring together a core group of professionals who could clarify the issues and make recommendations to clinicians, manufacturers, and regulatory or insurance agencies alike. They agreed that clinicians need simple and straightforward consensus advice on how to promote patient safety.

The chemical cycle of soda lime production, absorption of carbon dioxide, and regeneration of chalk was reviewed (see Figure 1). Chalk (calcium carbonate or CaCO<sub>3</sub>) is converted to lime (calcium oxide or CaO), while slaking with water converts lime to slaked lime (calcium hydroxide or Ca(OH)<sub>2</sub>). Gaseous carbon dioxide (in solution with water) reacts slowly with Ca(OH)<sub>2</sub>. Therefore, "soda" lime was created with the addition of the catalyst sodium hydroxide. This hydroxyl ion (OH-) reacts with carbon dioxide producing bicarbonate  $(HCO_3)$ , which then has strong affinity for Ca(OH)<sub>2</sub>, recreating chalk and regenerating the hydroxyl (OH-) catalyst. Other formulations of absorbent do not rely upon strong base to catalyze the reaction, but instead are using substances such as CaCl2 or CaSO4.

Numerous brands and formulations of absorbent are listed in Table 3. All contain a high concentration of Ca(OH)<sub>2</sub>. Discrepancies regarding their content exist in the literature. For example, legacy formulations of Sodasorb® (W. R. Grace and Company) had KOH, with NaOH below 4%. Current formulations have no KOH and the NaOH concentration is 3.7%. Sodalime variations also exist. Absorbent manufacturers have already developed products that produce insignificant or no compound A or carbon monoxide, whether moist or desiccated. They also produce minimal heat and minimally *ad*sorb volatile agents.

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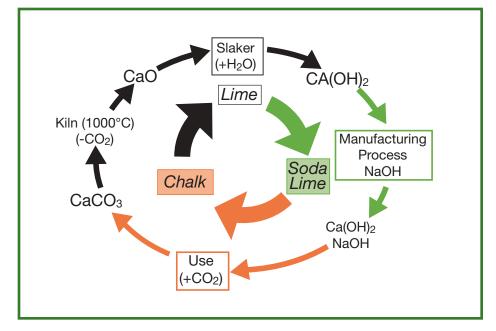


Figure 1: The Soda Lime Cycle, courtesy of Dr. Michael Clarke, Molecular Products

## **Consensus Statement Agreed Upon**

### "Absorbents," From Preceding Page

One absorbent provides a graded and permanent colorimetric indicator of both expected desiccation and exhaustion (Amsorb® Plus, Armstrong Medical Ltd.), while another (Spherasorb®, Intersurgical Ltd.) contains a substance that delays the total desiccation of the absorbent. Reducing by-products to negligible levels does not require strong-base-free absorbents.

The incidence of patient exposure to carbon monoxide is unknown. ECRI, Abbott Laboratories, and other investigators have already published recommendations to minimize the risk of unintended desiccation of absorbents. Anesthesia machine manufacturers are aware that fresh gas flow through modern and unique breathing circuits may promote desiccation of absorbent in different ways. Clinicians are directed to those resources for detailed information.

Monitoring absorbent temperature is one potentially useful adjunct, but the critical location of the probe and the quantity of heat that is worrisome have not been clearly identified. Temperature is elevated during normal carbon dioxide absorption reactions, and varies widely throughout the absorbent. Furthermore, carbon monoxide can still be produced at temperatures that might otherwise be associated with normal absorption. Relative humidity of the gas flowing out of the absorbent may be directly related to, and therefore indicate, its moisture content. Simple (home) devices to measure carbon monoxide are disrupted in the presence of volatile agents, but more sophisticated monitors are available. Some desiccated absorbents will continue to absorb carbon dioxide; therefore, the presence of an acceptable capnographic waveform should not be taken as confirmation that the breathing gas is free from carbon monoxide. Alternatively, an elevated baseline of inspired carbon dioxide on the capnogram should alert the clinician to the possibility of desiccation and/or exhaustion.

### **Consensus Statement**

At the conclusion of this conference, attendees were asked to again consider the goal of the conference, "to develop a consensus statement to share with anesthesia professionals on the use of carbon dioxide absorbents so as to reduce the risk of adverse interactions with volatile anesthetic drugs," and make appropriate recommendations. Based on those responses, the APSF drew the following conclusions:

The APSF recommends use of carbon dioxide absorbents whose composition is such that exposure to volatile anesthetics does not

### Table 1. Invited Medical Experts, APSF, and Industry Representatives

Medical Experts				
Jerry A. Dorsch, MD Jacksonville, FL	Edmond I Eger, II, MD Professor of Anesthesiology University of California, San Francisco, CA			
Evan D. Kharasch, MD, PhD Professor of Anesthesiology University of Washington School of Medicine Seattle, WA	Harvey J. Woehlck, MD Professor of Anesthesiology Medical College of Wisconsin Milwaukee, WI			
Anesthesia Patient Safety Foundation				
Robert C. Morell, MD Editor, APSF Newsletter	Michael A. Olympio, MD Chair, APSF Committee on Technology Co-moderator of Conference			
George A. Schapiro Executive Vice President	Robert K. Stoelting, MD President Co-moderator of Conference			
Industry Representatives				
Drug and Equipment Manufacturers Randall D. Ostroff, MD (Abbott Laboratories) Raul A. Trillo, Jr., MD (Baxter Healthcare) Christoph Manegold (Datascope) Juergen-Ralf Lange (Dräger Medical) Michael Mitton, CRNA (GE Healthcare)	<i>Carbon Dioxide Absorbent Manufacturers</i> Dr. Ciarán Magee ( <i>Armstrong Medical, Ltd.</i> ) Dr. Michael Clarke ( <i>Molecular Products, Ltd.</i> ) Mike Holder ( <i>Intersurgical, Ltd.</i> ) Eldon P. Rosentrater ( <i>Allied Healthcare</i> ) Jeffrey H. Mack ( <i>W.R. Grace</i> )			

result in significant degradation of the volatile anesthetic.

The APSF further recommends that there should be institutional, hospital, and/or departmental policies regarding steps to prevent desiccation of the carbon dioxide absorbent should they choose conventional carbon dioxide absorbents that may degrade volatile anesthetics when absorbent desiccation occurs.

In such circumstances of using absorbents that may degrade volatile anesthetics, conference attendees generally agreed that users could take the following steps, consistent with ECRI recommendations:

- 1. Turn off all gas flow when the machine is not in use.
- 2. Change the absorbent regularly, on Monday morning for instance.
- 3. Change absorbent whenever the color change indicates exhaustion.
- 4. Change all absorbent, not just 1 canister in a 2canister system.
- Change absorbent when uncertain of the state of hydration, such as if the fresh gas flow has been left on for an extensive or indeterminate time period.
- 6. If compact canisters are used, consider changing them more frequently.

There was also support for the APSF to create an "Expert Task Force" to define further the characteristics of carbon dioxide absorbents that do not significantly degrade volatile anesthetics.

Dr. Olympio is Professor of Anesthesiology, former Director and Founder of the Patient Simulation Laboratory, and former Vice Chair for Education for the Department of Anesthesiology at Wake Forest University School of Medicine in Winston-Salem, NC. He is also Chair of the APSF Committee on Technology and serves on the APSF Executive Board as well.

#### **Recommended References**

- Holak EJ, Mei DA, Dunning MB III, et al. Carbon monoxide production from sevoflurane breakdown: modeling of exposures under clinical conditions. *Anesth Analg* 2003;96:757-64.
- Olympio MA, Morell RC. Canister fires become a hot safety concern. APSF Newsletter 2003-04;18:45, 47-8.
- Fatheree RS, Leighton BL. Acute respiratory distress syndrome after an exothermic Baralyme-sevoflurane reaction. *Anesthesiology* 2004;101:531-3.
- Wu J, Previte JP, Adler E, et al. Spontaneous ignition, explosion, and fire with sevoflurane and barium hydroxide lime. *Anesthesiology* 2004;101:534-7.

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Editor's Note: There is not uniform agreement among experts as to the specific types and amounts of degradation products that may form when volatile anesthetics are exposed to desiccated absorbents that contain significant amounts of KOH and NaOH. Hence, no specific conclusions can be drawn from this conference about the relative contribution of any specific degradation product or circuit material [including plastics] as a combustible fuel in a high heat, oxygen-enriched environment.

### **Absorbent Composition Summarized for Conference**

### "Absorbents," From Preceding Page

- Castro BA, Freedman LA, Craig WL, Lynch C III. Explosion within an anesthesia machine: Baralyme, high fresh gas flows and sevoflurane concentration. *Anesthesiology* 2004;101:537-9.
- Woehlck HJ. Sleeping with uncertainty: anesthetics and desiccated absorbent. *Anesthesiology* 2004;101:276-8.
- Knolle E, Heinze G, Gilly H. Small carbon monoxide formation in absorbents does not correlate with small carbon dioxide absorption. *Anesth Analg* 2002;95:650-5.
- Woehick HJ, Dunning M III, Nithipatikom K, et al. Mass spectrometry provides warning of carbon monoxide exposure via trifluoromethane. *Anesthesiology* 1996;84:1489-93.
- "Dear Health Care Professional" Ultane® (sevoflurane) letter from Abbott Laboratories, November 17, 2003. Available at: www.fda.gov/medwatch/SAFETY/2003/ Ultane\_deardoc.pdf. Accessed June 27, 2005
- 10. Anesthesia carbon dioxide absorber fires. *Health Devices* 2003;32:436-40.
- Hazard update: revised recommendation for "Anesthesia carbon dioxide absorber fires" (published November 2003). *Health Devices* 2003;32:487.

### Table 2. Invited Observers

Invited Observers	
John Armstrong	Armstrong Medical
Jonnalee Bill	American Society of Anesthesia Technologists and Technicians
Joe Ciccone, PhD	
Robert Clark	
John T. Collins	
Albert L. de Richemond, MS, PE	ECRI
Jonathan Deutsch, MD	Baxter Healthcare
Charlotte Guglielmi, RN	Association of periOperative Registered Nurses
Robert Herdzina	
Steven Hoff	Abbott Laboratories
Elizabeth F. Holland	Abbott Laboratories
Gavin Keogh	Armstrong Medical
	Joint Commission on Accredition of Healthcare Organizations
Deborah Lawson, AA	American Academy of Anesthesiologists Assistants
Donald E. Martin, MD	American Society of Anesthesiologists
Marion McGowan	
Karen Meehan, RN	The Doctors Company
Vic Velton	
Tom Noonan	Allied Healthcare
John M. O'Donnell, CRNA	American Association of Nurse Anesthetists
Bonnie Reinke	GE Healthcare

### Table 3. Absorbent Comparisons

This table was formulated based on information supplied by the various manufacturers. The APSF assumes no responsibility for variations in, or deviations from the formulations that are represented in this table. The table is supplied for educational and conceptual purposes.

Company	Product Name	H <sub>2</sub> O%	NaOH%	KOH%	Ca(OH) <sub>2</sub> %	Significant Other	US Availability
Allied Healthcare/Chemetron	Baralyme®	11.0 – 16.0	0.0	<5	73	Ba(OH) <sub>2</sub>	No longer
Allied Healthcare	*Carbolime™	12.0 - 19.0	3	0.0	>75	—	Yes
W.R. Grace and Company	Sodasorb®	15.0 – 17.0	3.7	—	50 - 100	—	Yes
Intersurgical Ltd.	Intersorb Plus®	13.5 – 17.5	2.6	0.0	81	—	Yes
Intersurgical Ltd.	Spherasorb®	13.5 – 17.5	1.3	0.0	78	4% Zeolite	Yes
Intersurgical Ltd.	LoFloSorb®	13.5 – 17.5	0.0	0.0	78	6.5% Silica	Yes
Armstrong Medical Ltd.	Amsorb®	13.5 – 16.5	0.0	0.0	79 – 82	CaCl <sub>2</sub>	No longer
Armstrong Medical Ltd.	Amsorb <sup>®</sup> Plus	13.0 – 18.0	0.0	0.0	>80	CaCl <sub>2</sub>	Yes
Dräger Medical, Inc.	Drägersorb® 800	—	~2	~ 3	—	—	No longer
Dräger Medical, Inc.	Drägersorb <sup>®</sup> 800 Plus	~16	1 – 3	NA	75 – 83	—	Yes
Dräger Medical, Inc.	Drägersorb® Free	14 – 18	0.5 – 2	NA	74 – 82	CaCl <sub>2</sub>	Yes
Airgas†/Molecular Products	Sodalime	_	<3.5	2.6	>80	_	Yes
Molecular Products	Sofnolime®	12 – 19	<3.5	0.0	_	_	No‡
GE Medical <sup>†</sup> /Molecular Products	Medisorb™	_	<3.5	0.0	_	_	Yes

\*Manufactured by Molecular Products

+Distributor of product manufactured by Molecular Products.

‡Not available in US market as a medical product, although diving and military grades are available in the US. Medical grade is available outside US.

More than one manufacturer reported variable absorption capacity based on cannister design, shape, volume FGF, hydration, and carbon dioxide concentration. Nearly all reported price variability dependent upon marketing and type of fill.

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### Malignant Hyperthermia Syndrome: From Barnyard to Molecular Genetics Laboratory

#### by Henry Rosenberg, MD, CPE

Drs. M.A. Denborough and R.R. Lovell first formally described the syndrome we know today as malignant hyperthermia (MH) in a Letter to the Editor of *Lancet* titled "Anaesthetic Deaths in a Family" in 1960. They described a near fatality in a patient with a family history of deaths in apparently healthy individuals during or shortly after anesthesia. Once the syndrome was described, rapid progress was made in describing how, in certain individuals, anesthetic gases and succinylcholine could precipitate muscle rigidity, myonecrosis, acidosis, hyperthermia, and death. Families from all parts of the world were reported with this syndrome, which apparently followed an autosomal dominant inheritance pattern.

A major advance in the understanding of the pathomechanism of MH was the demonstration that various swine breeds develop a similar set of clinical signs, often in the absence of anesthesia, termed "Porcine Stress Syndrome" or "Pale, Soft Exudative Pork Syndrome." The pig model is similar in many ways to human MH, but different in others. Nevertheless it helped in the understanding of the clinical presentations of MH and in the demonstration of the efficacy of dantrolene in reversing the clinical signs of MH.

From the 1970s to the present, investigators in the United States, Europe, Australia, New Zealand, Japan, and South Africa enhanced our knowledge of the clinical description of MH, the characterization and standardization of the muscle biopsy contracture test, the demonstration of defective intracellular calcium flux in MH, and the differentiation of MH from other syndromes.

When the molecular genetic era dawned in the 1980s, several groups began the investigation of the molecular genetic defects responsible for MH. Using the pig model, David MacLennan's group at the University of Toronto was the first to demonstrate a consistent mutation in the gene that elaborates the ryanodine receptor in skeletal muscle (RYR-1). However, in humans it was soon apparent that many other mutations (the count at present is 23) in that gene and in others are causal for MH. In those patients with a positive halothane-caffeine contracture test for MH, approximately 30% of such patients were shown to harbor one of 15-20 known RYR-1 mutations. The good news is that the specificity of the mutation analysis is close to 100% in families at risk to MH.

The adaptation of mutation detection to clinical diagnostic testing started a few years ago in Europe. Guidelines for testing have been published by the European MH group (www.emhg.org).

In the spring of 2005, Prevention Genetics, a company located in Marshfield, WI, began offering

molecular genetic testing for MH in the US. The laboratory is CLIA and CAP certified.

There are several important issues to bear in mind when considering referral of a patient for MH testing by molecular techniques. First, the test is not a screening test. The sensitivity of the test in a population of patients with a positive contracture test is somewhere between 30 and 40%. Second, the absence of a mutation does not rule out MH susceptibility. Third, a referral for testing should be made only by a physician or genetic counselor. Fourth, a blood sample is all that is required for testing. Fifth, the test does not replace the contracture test. Because of the limited sensitivity of the genetic test, those without a mutation should be referred for contracture testing to determine MH susceptibility since the caffeine halothane test is very sensitive. And sixth, if one of the known mutations for MH is found in a family member, other family members with that mutation are MH susceptible for certain and may bypass the contracture test.

### Who Should Be Referred for Testing?

- A. Those patients with a positive caffeine halothane test or a confirmed clinical episode of MH.
- B. Those with an identified mutation as part of a research protocol.
- C. Family members of these patients listed above should also be considered for genetic testing after discussion with a biopsy center director or a genetic counselor.

Patients with a positive caffeine halothane test will first have their DNA assessed for the presence of 17 known mutations at a cost of about \$790. If one of the mutations is found, that mutation may be sought in specimens from family members. The cost for the assay for a specific mutation is about \$200. Reimbursement for such testing is dependent on the specific insurance company. Although not required, genetic counseling is advised for those undergoing genetic testing.

### What Are the Advantages of the Genetic Test?

Genetic testing will avoid the use of the invasive muscle biopsy contracture test. As such, it is less expensive than the contracture test and does not carry the morbidity of the muscle biopsy. Another advantage of such testing (in some cases) is the clarification of the likelihood that a perioperative morbidity or mortality is related to MH, since the DNA analysis may be performed on preserved tissue samples.

It is clear that with time, the sensitivity of the test will improve significantly. In an individual this may not require a repeat sample since the DNA analysis is based on sequencing the hot spots of the gene, and DNA variants of undetermined significance at this point may turn out to be causal for MH with further investigation.

Patients and physicians are urged to provide the North American MH Registry with a detailed clinical history in order to advance the understanding of the relation between clinical events and the molecular genetics of MH. Appropriate forms are available for this purpose by contacting the Registry (www.mhreg.org). The Registry database and collection vehicle are approved by the IRB of the University of Pittsburgh Medical Center and are in full compliance with regulations for protection of confidential medical information.

The MHAUS board and Professional Advisory Council and hotline consultants are very pleased with the introduction of genetic testing for MH in North America. Nevertheless, we realize that this is just the first step in devising a highly sensitive, specific, minimally invasive diagnostic test for MH. We also expect that other laboratories will offer clinical genetic testing for MH in the near future.

Further information on the test, including Frequently Asked Questions, may be found on the MHAUS website (www.mhaus.org) or by contacting MHAUS directly.

Dr. Rosenberg is President of the Malignant Hyperthermia Association of the United States (MHAUS) and Director of the Department of Medical Education and Clinical Research at the St. Barnabas Medical Center in Livingston, NJ. He is also a Professor of Anesthesiology at Mt. Sinai School of Medicine, NY.

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## **MHAUS Reports 3 Unique Cases of Hyperkalemic Cardiac Arrest**

by Henry Rosenberg, MD, CPE, Arjunan Ganesh, MD, Albert J. Saubermann, MD, and Susan C. Nicolson, MD

The Malignant Hyperthermia Association of the United States (MHAUS) is a patient advocacy organization that has operated a "hotline" since 1982 staffed by volunteer anesthesiologists with expertise in the management of this rather unusual, potentially fatal syndrome. Fortunately, cardiac arrest and death related to malignant hyperthermia (MH) have been rare, thanks to early detection of the syndrome by capnography, and education of the anesthesia community to the early signs of the disorder as well as the availability of dantrolene, the specific antidote for the metabolic effects of MH.

In the early 1990s members of the professional advisory committee of the MHAUS recorded several cases of sudden hyperkalemic cardiac arrests in young males (generally <5 years of age) during or following anesthesia. Investigation revealed that most were in the asymptomatic or minimally symptomatic stage of Duchenne muscular dystrophy (DMD). The mortality associated with this syndrome was 60%.<sup>1</sup> In most cases, the cardiac arrest occurred following the administration of succinylcholine after induction of anesthesia with an inhalation anesthetic. A report to the FDA led to a change in the package insert of succinylcholine and a black box warning concerning the use of succinylcholine in children.

Even at that time, however, there were sporadic cases in this population of hyperkalemic arrest during or immediately following general anesthesia in the absence of succinylcholine. We would now like to report 2 apparently asymptomatic male patients who sustained hyperkalemic cardiac arrest in the postanesthesia care unit (PACU) where the anesthetic was conducted with sevoflurane in the absence of succinylcholine. In addition, a third patient, a young female, developed sudden hyperkalemic cardiac arrest following a minimal dose of succinylcholine to treat laryngospasm at the conclusion of surgery. All of these cases occurred over a period of 7 months.

 The first patient was a 4-year-old male who underwent uneventful atrial septal defect repair using sevoflurane anesthesia for induction followed by isoflurane for maintenance. The non-depolarizing neuromuscular blocking agent was pancuronium. The procedure lasted for 2 hrs 45 min, including a 29-min bypass time. Following the procedure, he entered the recovery room and met the criteria for extubation, and the trachea was extubated. The patient was awake, alert, and breathing regularly with an oxygen saturation of 100% at the time of extubation. Twenty minutes later, the ECG showed broad complex bradycardia that rapidly progressed to ventricular tachycardia and fibrillation, which responded to defibrillation (20 J). The patient was reintubated. Serum potassium concentration during resuscitation was >9 mEq/L on the first arterial blood gas with a base deficit of -4.3 mmol/L. The child's esophageal temperature was 37.7 °C. The patient received intravenous (IV) calcium gluconate, sodium bicarbonate, and a glucose-insulin infusion. Serum creatine kinase (CK) within an hour of the arrest was 17,821 U/L, and peaked at 613,120 mEq/L 48 hours postoperatively. The urine was noted to be pale pink in color. As advised by the MH Hotline consultant, dantrolene was withheld, as there was no evidence of hypermetabolism. The ventilatory requirements were normal, and there was no evidence of increased carbon dioxide production.

Subsequent molecular genetic analysis of a peripheral blood sample demonstrated a deletion in the dystrophin gene from at least exon 47 to exon 52 (exons 45 and 60 were present), which is consistent with a diagnosis of DMD. There was no history of musculo-skeletal developmental delays or any abnormality on clinical examination.

- 2. The second patient was a 5-year-old male weighing 19-kg with a history of hereditary spherocytosis. He underwent uneventful laparoscopic splenectomy with general endotracheal anesthesia with sevoflurane, nitrous oxide, and vecuronium. In the PACU he sustained a cardiac arrest with potassium of 9.2 mEq/L. One CK was elevated to 23,000 IU; testing of a blood sample drawn preoperatively revealed a CK of 15,000 IU. Following prolonged resuscitative efforts, the cardiovascular system stabilized. However, the patient sustained significant neurologic damage, oliguric renal failure, and expired. It was unclear from the family history as to whether there were any signs of myopathy or family history of muscular dystrophy. Histologic examination of the muscle revealed changes typical for DMD.
- 3. The third patient was a 7-year-old, 30-kg, asymptomatic **female** who developed laryngospasm at the end of general endotracheal anesthesia for tonsillectomy and adenoidectomy with sevoflurane anesthesia without muscle relaxant. Succinylcholine (6 mg) was administered, and ventricular fibrillation ensued. Prompt treatment with glucose, insulin, bicarbonate, hyperventilation, and calcium chloride combined with defibrillation restored

normal sinus rhythm. The potassium level peaked at >9 mEq/L, and the CK peaked at 150,000 IU. The patient left the hospital fully recovered. No evidence of myopathy has been determined at the present time.

We report these findings in order to underline that young patients with asymptomatic dystrophinopathy may develop hyperkalemic cardiac arrest in the absence of succinylcholine when potent volatile agents are used. Of special interest in these cases is that the cardiac arrest occurred not during surgery but in the PACU. In addition, in the one case the hyperkalemic cardiac arrest after succinylcholine occurred in a female.

One lesson from these and similar cases is that therapy for sudden cardiac arrest in a young child during anesthesia or in the PACU, in the absence of airway compromise, hypovolemia, or known cardiac abnormalities, should be directed at hyperkalemia. Evidence of myoglobinuria and hyperkalemia should be sought and the patient treated accordingly. Whether precipitated by succinylcholine or not, the presumptive diagnosis of occult myopathy should be entertained, specifically a dystrophinopathy.

Often sudden cardiac arrest in the perioperative period in an otherwise asymptomatic child is thought to represent an episode of MH and treatment with dantrolene is instituted. However, clinicians should consider hyperkalemia to be a more likely reason. Cardiac arrest related to MH is usually preceded by rapidly rising end-tidal carbon dioxide, muscle rigidity, acidosis, and hyperthermia, and most often occurs during anesthetic administration rather than in the postoperative period. In such cases, the cause of the cardiac arrest is usually related to significant metabolic and/or respiratory acidosis rather than hyperkalemia.

Package insert and other drug information concerning potent inhalation anesthetic agents (i.e., sevoflurane, desflurane, halothane, and enflurane) should emphasize that when unexpected sudden cardiac arrest occurs in a young child, hyperkalemia is a likely precipitating cause, even in the absence of succinylcholine. Myoglobinuria should be considered, and the patient evaluated for an occult myopathy, especially DMD.

Dr. Rosenberg is President of the Malignant Hyperthermia Association of the United States (MHAUS) and Director of the Department of Medical Education and Clinical Research at the St. Barnabas Medical Center in Livingston, NJ. He is also a Professor of Anesthesiology at Mt. Sinai School of Medicine, NY.

### Letter to the Editor

## **Stand Near By in the MRI**

To the Editor:

I am writing to suggest it may be appropriate for the ASA/ASPF to specifically address monitoring standards for the provision of sedation, anesthesia, and ventilation of patients in the magnetic resonance imaging (MRI) suite. When I heard Irene P. Osborn, MD, Director (Division of Neuroanesthesia, Mount Sinai Medical Center, NY, NY), speak at the California Society Refresher Course in San Diego earlier this year, I specifically asked if it was appropriate to monitor the patient, not from the scanner room itself (where the patient is in the scanner tube), but from the scanner control room (SCRthe room next door with all controls separated by a wall with a large dark glass window). This question was answered informally by those in attendance, with more than 50% of the attendees (including Dr. Osborn) indicating this was their practice for adult and pediatric patients. I believe this indicated that, typically, NO provider remained in the scanner room itself with the patient-MD or CRNA. I believe this is in contradiction to ASA basic standards for monitoring, which make no provision for such exception. The Standard reads:

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

Having had opportunity to practice in multiple private and university settings since my graduation from medical school in 1981, I have seen many developments in providing anesthesia for MRI over the years. Historically, many standard items were not "MRI compatible," yet were made available in the scanner room with exceptional precautions. Until I came to this university center, I had always remained in the scanner room with my patients under anesthesia and had never seen anesthesia provided from the scanner control room, although this methodology was "standard" at Presbyterian University Hospital in Pittsburgh when I arrived. Here infusion and ventilator tubings were run through wall portholes at distances of 40 feet, and of course, direct monitoring of the patient was not done, but rather the anesthesia machines and telemetric monitor screens in the SCR room were observed. I was for a time, however, able to practice MRI anesthesia from within the scanner room using "non MRI approved" pumps and anesthesia machines maintained at a safe distance from the magnet. In this way, all aspects of anesthetic care could be directly observed and actively managed, as in the operating room and per ASA guidelines.

### MRI Death Reinforces Precautions

This all changed drastically in 2001, when a child died in the Westchester Medical Center in New York

State, after being hit in the head in the MRI scanner by a ferromagnetic oxygen cylinder. I was suddenly personally confronted with absolute restrictions prohibiting anything "non-FDA approved MRI compatible" from entering the scanner room. I was suddenly forced out into the SCR with my "magnetic" equipment, monitoring at 40 feet from the SCR, which created great anxiety to apparently only myself. In the past decade, I am aware of 2 deaths having occurred in this city using these "40 foot/next door" techniques: 1) the expiratory limb of a circle system occluded and the patient succumbed to tension pneumothorax, and 2) a mini-drip infusion of propofol (no volumetric pump) ran uncontrolled with a fatal outcome. Astonishingly, a picture of a mini-drip propofol infusion (without volumetric pump) of this kind is pictured, as well as "monitoring from the scanner control room" in a recent MRI-anesthesia review article.1

### Incident Illustrates Need for Monitoring

More astonishing is that modern MRI suites continue to function with antiquated equipment, although modern and MRI-compatible operating room suites have been introduced in the US and Europe!<sup>2,3</sup> Here all anesthetic and surgical needs are met in the scanner room itself. MRI-compatible equipment has now been procured here at my institution, including infusion pumps and MRI ventilators. Anesthesia personnel should now remain in the room, as no biological hazard exists to normal human beings in the scanner room, especially at 10 feet from the magnet coil.<sup>4</sup> However, individuals continue, by choice, to monitor from the SCR. This recently led to the following incident:

A patient was brought to the MRI from the radiology suite after coils were inserted in an aneurysm of the carotid artery. This 70-year-old female came intubated, paralyzed, with a radial arterial catheter, and on a propofol infusion. The infusion was switched to the MRI compatible, battery operated pump, and she was ventilated with the ventilator without ETCO<sub>2</sub> analysis. Neither piece of equipment is electrically connected to alarms visible or audible in the SCR. The arterial pressure trace could not be displayed, because no MRI compatible transducers were available in the institution. The ETCO<sub>2</sub> was not monitored, as this was not routine for this ventilator type; however, an airway pressure gauge was connected and viewable in the SCR via 40-foot tubing. The MRI department's monitor is capable of both arterial tracing and ETCO<sub>2</sub>, as well as non-invasive blood pressure (NIBP), ECG, and pulse oximetry, and all monitored parameters are viewable both in the SCR and scanner room.

After a short period in the scanner, the NIBP was not obtaining results, and a second stat attempt vielded no result. The airway pressure was now noted to cycle between 20-40 torr and at a rate of 30-40. This was noted from the SCR, and after a short interval to interpret the situation and to enter the scanner room, the patient was withdrawn urgently from the scanner. At this time, no radial pulse was detected, although heart and breath sounds were present. Recycling the BP cuff yielded 44/20, immediately after which she was placed on bag-valve ventilation, while no visible or auscultatory problems were noted with ventilation. Phenylephrine was obtained from the SCR. Before the phenylephrine could be administered, renewed NIBP measurement now yielded 169/110. The propofol infusion pump was noted to display a red light indicating "downward occlusion" of the CVP line — duration unknown. A second MRI ventilator was obtained, propofol reinstituted, and the patient returned to the scanner for scan, with the anesthesia provider instructed to remain at the patient's side.

The first ventilator was isolated for inspection and found to function within parameters. These ventilators are gas powered, non-electrical/ mechanical ventilators using "Bird-1970s technology." The problem appeared to be due to changes in patient compliance resulting in "autocycle" of unwanted, yet available, SIMV programming, atypical of anesthesia ventilators. These ventilators are managed by the respiratory therapy department and are unfamiliar to anesthesia personnel. This incident resulted in a period of hypoperfusion from the sustained high airway pressures, a "valsalva maneuver" of sorts, as well as the potential for awareness due to interruption of the propofol infusion. The interruption of the propofol may have been lifesaving in this situation (as well as perhaps causative). Had the anesthesia provider been present in the room, the rapid cycling of the mechanical ventilator and audible alarm of the infusion pump would have been noticed. Visual observation from the SCR is significantly impaired by the reduced transparency of the glass windows, which are part of the Faraday cage screen for radiofrequency energy, and audio alarms typically remain unheard in the SCR. Emphasis on the use of audible alarms has been recently noted, and MRI alarms may need to be much louder than in the OR, due to the significant scanner noise.5 Had the arterial trace been available, earlier recognition might have prevailed in this instance, but as the NIBP was cycling at 5-minute intervals, a significant period

## PCA Presents Serious Risks

### To the Editor:

A healthy 26-year-old soccer player undergoes cruciate ligament repair and is discharged to the floor with patient-controlled analgesia (PCA). His mother, concerned that he rest comfortably after poor postoperative pain control, repeatedly presses his morphine PCA button while he is asleep. He stops breathing and is resuscitated, albeit with a hypoxic brain injury.

A mother of 3 small children with chronic lower back pain, for which she takes Percocet<sup>TM</sup>, undergoes uneventful emergency appendectomy and is discharged to the floor on hydromorphone PCA. Frustrated by her difficult pain management, floor nurses give supplemental intravenous hydromorphone outside of PCA parameters. She suffers a respiratory arrest and hypoxic brain injury.

Almost 20 years after the APSF spearheaded the adoption of pulse oximetry and capnography as standards for patient monitoring in the OR,<sup>1</sup> and with a resultant decrease in catastrophic respiratory events,<sup>2</sup> I still encounter such cases as an expert witness in defense of hospitals liable for these devastating outcomes.

### PCA by Proxy Presents Great Danger

There is accumulating evidence that PCA presents serious risks to patients and liability exposure to hospitals. The 2 main safety mechanisms integrated in current PCA pumps, the lock-out interval and maximum dose limit, fall woefully short of preventing overdosage of narcotics. PCA "by proxy," in which family members or persons other than the patient administer bolus doses, as occurred in the example above, are well documented.<sup>3</sup> The risk of patient harm due to medication errors with PCA pumps, the most common form of PCA error, is 3.5times the risk of harm to a patient from any other type of medication administration error.<sup>4</sup> The FDA's Manufacturer and User Facility Device Experience (MAUDE) Database for 2004, a voluntary database for reporting problems with devices, reports 21 deaths related to PCA pumps versus 16 deaths for all other large volume infusion pumps (LVP).5 The installed number of LVPs is approximately 10-times greater than the number of PCA pumps, suggesting the risk of death from an adverse event with a PCA pump is at least 10-times greater than with LVPs. Recent University Hospital Consortium (UHC) survey data found that 9 of 15 members who responded to a survey identified recent PCA adverse events as potentially costly in terms of liability exposure.

The 2004 ASA Annual Meeting (www.asaabstracts.com) featured many "better mousetraps" for pulse oximetry, capnography, and systems to prevent and intervene in respiratory insufficiency. Yet somehow, all this technology stops at the post-anesthesia care unit (PACU) door, and patients are sent to the hospital floor with their narcotic laden infusions, where currently acceptable standards of monitoring are a flow sheet with vital signs and pump data that are manually updated at best every 30 minutes. The patient's only safety net is the mayday team, an often poorly choreographed band of practitioners left to initiate resuscitation at an often undetermined period of time after the critical event.

In the mid 1990s, management of acute postoperative pain and PCA was, in effect, transferred to the surgical service when the government (HCFA/CMS) and private insurers stopped compensating anesthesiologists for managing postoperative pain. It was left to the surgeons to manage pain, narcotics, and respiratory insufficiency. Yet if you asked first-year medical students which specialist is the expert in pain, narcotics, respiratory physiology, and resuscitation, they would reply 'anesthesiologist," not "surgeon," "internist," or "hospitalist." We define ourselves as perioperative physicians,6 yet in the ever increasing number of hospitals without an anesthesia-run acute pain service, patients are discharged from the PACU with PCA technology that exposes them to great risk without our oversight.

### Capnography May Warn of Hyperventilation

Some may argue that my experience lacks a denominator, and that these may be rare events. I contend that one such adverse outcome in a friend or family member undergoing elective surgery is one too many. Cashman et al., in a recent meta analysis of the literature, reported an incidence of "respiratory depression" of 11.5% by oximetry (O<sub>2</sub>Sat <90%) and 1.3% by bradypnea (RR <10), which translates to thousands of patients with potentially catastrophic respiratory depression per day.7 Others take comfort in using oximeters in "high-risk" patients, yet this is a deceptively ineffective approach. The first patient above could hardly be described as "high risk." Furthermore, Stemp recently highlighted the dangers of simply adding supplemental oxygen, the typical "therapeutic" response to desaturation.8 Supplemental oxygen does not treat desaturation due to hypoventilation, but merely postpones the patient's insidious progress from bradypnea to apnea. The addition of a capnograph, however, may anticipate a patient's desaturation by warning of a decrease in respiratory rate and rise in end-tidal carbon dioxide. In the OR setting, these monitors together were judged to potentially prevent 93% of respiratory mishaps in the closed claims database.<sup>2</sup>

Perhaps the APSF could take a more active role in measuring the scope of the problem, propose monitoring guidelines for PCA, and encourage development of technology that closes the monitoring void that exists with PCA. It would once again demonstrate that it is the premier organization devoted to patient safety in the perioperative environment.

Frank J. Overdyk, MSEE, MD Charleston, SC

#### References

- Pierce EC. The establishment of the APSF and the ASA Closed Claims Study. The 34th Rovenstine Lecture. Available on the web at: http://www.apsf.org/about/ rovenstine/part1.mspx. Accessed on April 26, 2005.
- Tinker J, Dull D, Caplan RA, et al. Role of monitoring devices in prevention of anesthetic mishaps: a closed claims analysis. *Anesthesiology* 1989;71:541-6.
- Sidebotham D, Dijkhuizen M, Schug S. The safety and utilization of patient-controlled analgesia. J Pain Symptom Manage 1997;14:202-9.
- Sullivan M, Phillips MS, Schneider P. Patient-controlled analgesia pumps. USP Quality Review 2004;81:1-3. Available on the web at: http://www.usp.org/ pdf/patientSafety/qr812004-09-01.pdf. Accessed April 25, 2005.
- Manufacturer and User Facility Device Experience Database - (MAUDE). U.S. Food and Drug Administration, Center for Devices and Radiologic Health, Department of Health and Human Services. Available on the web at: http://www.fda.gov/cdrh/maude.html.
- Alpert CC, Conroy JM, Roy RC. Anesthesia and perioperative medicine: a department of anesthesiology changes its name. *Anesthesiology* 1996;84:712-5.
- Cashman JN, Dolin SJ. Respiratory and haemodynamic effects of acute postoperative pain management: evidence from published data. Br J Anaesth 2004;93:212-23.
- Stemp L. Etiology of hypoxemia often overlooked. APSF Newsletter 2004;19(3): 38-9.

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### **Dear SIRS**

## **Descending Bellows Drives Question**





Michael Olympio, MD, Chair of the APSF Committee on Technology and Co-Founder of the SIRS Initiative.

Dear SIRS refers to the Safety Information Response System. The purpose of this column is to expeditiously communicate technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by Drs. Michael Olympio, Chair of the Committee on Technology, and Robert Morell, Editor of this newsletter. Dr. Olympio is overseeing the column and coordinating the readers' inquiries and the responses from industry. **Dear SIRS** made its debut in the Spring 2003 issue.

### Dear SIRS:

We are currently evaluating new anesthesia machines for purchase. One of the models is a 2005 Datascope Anestar model. It has a hanging bellows.

The company states that the hanging bellows is no longer a concern. The uncoupling of the fresh gas flow means that an increase in fresh gas flow will NOT increase the tidal volume.

Do you have any resources, evaluations, or comments about the hanging bellows on the new machines? Dräger and Datex-Ohmeda do not have this type of bellows.

David A. Ciochetty, MD Director, Anesthesia Department Passavant Area Hospital Jacksonville, IL

### **Response:**

### Dear Dr. Ciochetty,

Datascope appreciates the opportunity to respond to your inquiry about descending bellows and their relationship to a fresh-gas decoupled anesthesia circuit. However, before I get into the technical description of the Anestar's circuit, I would like to unequivocally state that any modern anesthesia machine, marketed in the U.S. today, including the Anestar, is safe regardless of which ventilation technology is being employed. Information to the contrary may be outdated or intended to mislead.

As cost-effective sensor technology and embedded software have been integrated into anesthesia machines over the recent past, clinicians have benefited from new functionality unattained in previous generations of anesthesia delivery equipment. More importantly, such technology adds and automates an increased level of vigilance, with the ultimate benefit of increasing patient safety. Similarly, I am reminded of how driver safety is improved in a modern automobile through accepted invisible features such as ABS and traction control. All anesthesia systems on the market today control the fresh gas flow within the breathing cycle to achieve constant tidal volume delivery. In part, they depend on their alarm technology and other monitoring, such as capnography, to alert the user in case of disconnects or leaks.

Besides accepted visual indications of disconnects and leaks, manufacturers nowadays include additional alarms to appropriately alert the user. Several national and international standards have been developed to increase the safety and reliability of such indications. Datascope's Anestar has alarms which specifically indicate the following conditions:

- Breathing circuit disconnect
- Peak pressure below minimum pressure alarm
- Tidal volume lower than VT<sub>min</sub>
- · Minute volume below alarm limit
- Ambient air intake: check fresh gas setting.

These alarms are in addition to a graphic, breath-by-breath, display of the pressure wave-form.

Besides the electronic vigilance, in the case of a fresh-gas decoupled system, the physical/visual indication has shifted from the bellows to the reservoir (breathing) bag, which is always in the circuit. During normal operation, the bag has a full appearance and appears to pulsate, inflating slightly during inspiration and returning to normal volume during expiration. But, in case of a disconnect, or a major leak, the bag will deflate after a few breaths, simulating the behavior of ascending bellows.

If the leak is less than the fresh gas flow, the bag (reservoir) will supplement the fresh gas flow, while continuing to ventilate the patient and the bag will appear to pulsate more deeply. Since, indirectly, leaks are an implied topic of this discussion, I would like to point out that the Anestar breathing circuit, including the ventilator, absorber, valves, and sensors, are implemented in a module within a single aluminum block virtually eliminating the possibility of internal system leaks. Furthermore, the breathing module is warmed to 35°C to prevent condensation from occurring within the breathing circuit and the bellows.

At this point, I would like to provide a brief description of the operation of the Anestar's fresh gas decoupling breathing circuit. Simply stated, a fresh gas decoupled anesthesia circuit delivers the set tidal volume to the patient independently of the fresh gas setting. We believe that the accurate delivery of set tidal volume is clinically important, especially when ventilating children.

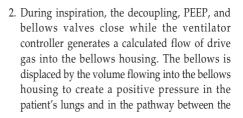
In such a circuit, the bellows, reservoir bag, and decoupling valve facilitate a straightforward way to implement this technology without the need for external sensors and a feedback mechanism. In addition, this circuit's configuration also facilitates a compliance compensation method, which corrects for compliance deviations external to the breathing module (e.g., patient's breathing hoses).

## Fresh Gas Decoupling Minimizes Complexity

### "Bellows," From Preceding Page

Following the Anestar's simplified schematic representation:

1. When activated, the ventilator is immediately ready to deliver volume to the patient.



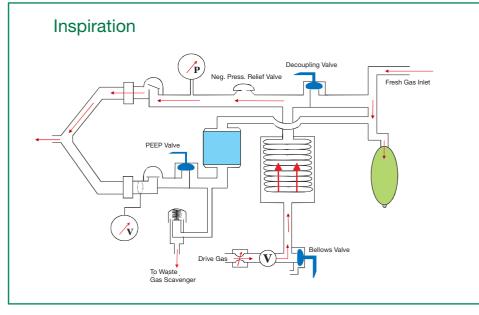


Figure 1: Anestar Simplified Schematic Representation During Inspiration

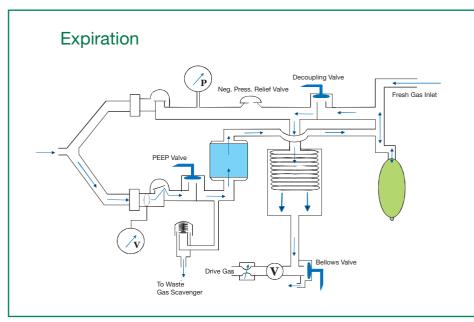


Figure 2: Anestar Simplified Schematic Representation During Expiration

decoupling and PEEP valves. The carbon dioxide absorber, APL valve, and reservoir bag are isolated from the patient circuit. During inspiration, fresh gas flows into the reservoir bag. Once the bag is filled, excess gas flows out the waste gas scavenger. Airway pressure is monitored inside the breathing module, and is additionally used to compensate for compliance.

3. During expiration, based on the selected breath rate and I:E ratio, the decoupling, PEEP, and bellows valves open to allow gas to flow. At that time, the ventilator controller stops the flow of drive gas to the bellows housing. When these valves open, exhaled gas flows back through the one-way expiratory valve and carbon dioxide absorber. Based on the fresh gas flow rate, a portion of the exhaled gas flows out the APL and a portion is re-circulated. During exhalation, fresh gas flows through the open decoupling valve to refill the bellows, as the drive gas volume in the bellows housing is vented through the open bellows valve. As the bellows falls, gas is sourced from the fresh gas inlet first, which is the path of least resistance. The next source of gas is the gas returning from the absorber, and only if there is an interruption in the fresh gas source is gas drawn from the bag. The gas flow priority scheme, described above, is facilitated by the design of the Anestar's breathing module. Exhaled volume is measured by a hot wire sensor located inside the breathing module, near the expiratory valve.

In summary, Dr. Ciochetty, the descending bellows is an essential part of the Anestar's safe, stateof-the-art, reliable, and cost effective anesthesia circuit.

Fresh gas decoupling keeps complexity to a minimum and offers the clinical advantage of maintaining the set tidal volume independently of the fresh gas flow.

Respectfully Submitted,

### Abe Abramovich

Director, Anesthesia Systems Development Datascope Corp., Patient Monitoring Division Mahwah, NJ

> New APSF web address: www.apsf.org

## MRI Requires New Video Drives Home High Vigilance Dangers of Substance Abuse

### "MRI," From Page 32

of compromise of up to 10 minutes may have occurred. The patient was not found to have sustained awareness or other lasting injury upon emergence.

In conclusion, it would seem appropriate to have specific national standards for MRI anesthesia which meet general published OR guidelines. Education of colleagues regarding the complete lack of danger in the MRI for personnel without metal implants appears necessary, while individuals with contraindications to undergo MRI scanning may need to exclude themselves from work in this area. MRI-compatible equipment can seem very expensive, until the cost of the scanner or patient death puts it into perspective. Equipment chosen by MRI departments may be so foreign to anesthesia personnel (as in this instance) as to present an additional danger due to non-familiarity. Oddly enough, even some of these MRI-approved devices are highly magnetic and non-"MRI-FDA approved devices" have been used safely for years. Modern standards should enhance safer, modern anesthesia techniques and may serve to facilitate the acquisition of appropriate equipment in financially trying times. Anesthesia safety should not be compromised by historic patterns, unfounded fears, or a reluctance to remain at the side of the patient without specifically identified dangers. The separation of anesthesia providers and equipment from the patient's side in the MRI suite should be relegated to the annals of history.

Paul M Kempen, MD, PhD Pittsburgh, PA

### References

- Gooden CK, Dilos B. Anesthesia for magnetic resonance imaging. Int Anesthesiol Clin 2003;41:29-37.
- Hall WA, Liu H, Martin AJ, et al. Safety, efficacy, and functionality of high-field strength interventional magnetic resonance imaging for neurosurgery. *Neurosurgery* 2000;46:632-42
- Schmitz B, Nimsky C, Wendel G, et al. Anesthesia during high-field intraoperative magnetic resonance imaging experience with 80 consecutive cases. J Neurosurg Anesthesiol 2003;15:255-62.
- Menon DK, Peden CJ, Hall AS, Sargentoni J, Whitwam JG. Magnetic resonance for the anaesthetist. Part I: Physical principles, applications, safety aspects. *Anaesthesia* 1992;47:240-55.
- 5. Stoelting RK: APSF stresses use of audible monitor alarms. *ASPF Newsletter* 2004;19:1, 19.



#### by Robert C. Morell, MD, Editor

Drs. Tom Hornbein, Raymond Roy, and Lynn Hankes along with Diana Quinlan, CRNA, served as Executive Directors for the new video Wearing Masks II. The video, produced by the Coalition for the Prevention of Substance Abuse in Anesthesia, is an excellent educational tool illustrating the dangers of substance abuse and drug addiction in anesthesia. Specific focus is directed toward behavioral patterns that may be recognized in impaired health care professionals along with signs of addiction. The goal of this presentation is to help identify addicted anesthesia providers and help them enter safe and anonymous treatment. This video is available in DVD format and has 5 parts, which include an introduction, the original Wearing Masks I video, discussion questions, Wearing Masks: Ten Years



Later, and resource information. The content is personal, dramatic, and extremely important. The destructive forces of drug addiction are presented through the eyes of family, friends, and coworkers of real anesthesia providers whose lives were destroyed, and ended, by substance abuse. During our careers, we will all likely encounter a colleague or coworker who is an addict. Education may help us recognize the problem and intervene appropriately. During my 22 years in anesthesia, I have personally known 4 anesthesia providers who were addicts: 2 physicians, and 2 CRNAs. One physician was resuscitated after being found in full arrest with a needle in his arm, 1 CRNA fell unconscious while administering a general anesthetic, and 1 anesthesia resident (who appears on this video) is now dead, despite intervention and multiple attempts at treatment and rehabilitation. This is a real problem, affecting real people, and impacting patient safety in a dramatic way. Wearing Masks II is a tremendous educational tool that all anesthesia providers should watch. Contact and ordering information is available from the website www.allanesthesia.com.

SAAC/AAPD (Society of Academic Anesthesiology Chairs/the Association of Anesthesiology Program Directors) has also recently produced a DVD entitled *Collateral Damage: Drug Abuse and Anesthesiology.* Contact and ordering information for this video is available from the website www.aapd-saac.org. Finally, a recent article in JAMA by Domino, Hornbein, et al.<sup>1</sup> examined risk factors for relapse in health care professionals with a history substance abuse.

#### Reference

 Domino KB, Hornbein, Polissar NL, et al. Risk factors for relapse in health care professionals with substance use disorders. JAMA 2005;293:1453-60.

### A Statement by the Executive Committee of the APSF

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

## Syringe Reuse Transmits Infection

#### by Rodney Lester, PhD, CRNA

News reports in September 2002 revealed that clusters of patients in Oklahoma, Nebraska, and New York had been diagnosed with Hepatitis C. The common element in all 3 of these outbreaks was that syringes and needles had been reused, including the injection of an expensive or controlled drug into the IV line of more than 1 patient in order to avoid "wasting" medication. Even more troubling were the anecdotal reports that these were not isolated incidents—that the practice was not only permitted, but encouraged, as a cost-saving measure. Infection control specialists saw the reusing of syringes and needles as part of the culture in some areas of practice and had given up trying to change it.

In response to these events, the American Association of Nurse Anesthetists (AANA) convened a task force to develop a series of short-term and long-range strategies to address this serious patient safety issue. The following are some of the strategies suggested for further consideration:

- educating providers and consumers as to the proper use of devices and the consequences of misuse
- issuing of a joint statement by health care organizations condemning the practice and citing best practices
- conducting more research into the practice to determine how prevalent misuse is
- identifying the gap between infection control standards and compliance with standards, i.e., why is misuse happening and what can be done about it
- inspecting the use of syringes and needles as part of the JCAHO and Magnet processes
- publishing a booklet or manual on use and misuse of needles and syringes.

As the initial step, the AANA sent more than 40,000 letters with copies of Infection Control Guidelines to all CRNAs, nurse anesthesia students, and program directors to raise awareness of this issue and urge strict adherence to the guidelines. Letters were also sent to the CEOs of hospitals and ambulatory surgery centers urging them to take an active role in assuring compliance with infection control guidelines. The AANA also developed a series of educational offerings addressing infection control, which continue to be presented.

### Survey Reviews Continued Syringe Use

In October 2002, a telephone survey was conducted by Cooper Research to determine the scope of the problem on needle and syringe reuse by health care providers. The survey findings revealed that 1 in 100 of those surveyed reuse the same needle and/or syringe on multiple patients. These findings indicate that millions of patients per year were being exposed to used needles and syringes potentially contaminated with life-threatening disease organisms. The study also indicates that there is a great deal of confusion regarding proper syringe and needle usage among all health care providers.

The AANA sent letters and press releases to the American Hospital Association, American Medical Association, American Society of Anesthesiologists, American Dental Association, American Association of Oral and Maxillofacial Surgeons, American Nurses Association, and Nurse Organizational Alliance to inform them of the issue and to invite them to join in developing an agenda for an upcoming patient safety initiative. Involvement of the Anesthesia Patient Safety Foundation was discussed with foundation leadership. In addition, the AANA initiated a project to solicit input from selected national health care organizations, accrediting agencies, federal government agencies, and medical and nursing professional organizations. The goal of this collaboration was to identify actions to date, identify additional strategies to address the reuse issue, and gauge interest in participation with AANA and other stake holders on future initiatives.

An article entitled "Transmission of Hepatitis B and C Viruses in Outpatient Settings—New York, Oklahoma, and Nebraska, 2000-2002" appeared in the September 26, 2005, issue of *Morbidity and Mortality Weekly Report*. The article noted the AANA initiative and stated, "CDC is working with professional organizations, advisory groups, and state and local health departments to address these issues."

### **JCAHO Plans to Raise Awareness**

In late 2003, a project was completed by AANA that surveyed national health care organizations, accrediting agencies, federal government agencies and medical and nursing professional organizations. The majority of organizations responding to the survey indicated that they thought targeted educational initiatives to improve infection control practices related to syringe and needle reuse were needed. Nursing organizations offered to collaborate with the educational initiatives. The following excerpts from the final report reflect some of the findings:

"Most organizations report that they are making the information about needle/syringe reuse available to leaders and members through publications and web sites. Several organizations pointed to their position statements on infection control standards as their position on the issue including the American Hospital Association (AHA). AHA reported that the issue is one of reprocessing and not reuse of devices, noting that a caregiver who takes a syringe/needle, presumably labeled as a single use medical device, and uses it more than once (on a different patient) is engaging in reuse of a single use device. . . unless the syringe/needle is reprocessed. If a caregiver is simply using it again and again. . . it is a clear violation of federal regulations. The American College of Healthcare Executives reported that they would not take a position on the issue but would look to AHA to address the matter. The American Organization of Nurse Executives remarked that they learned of this matter from AANA and had distributed the information to members. The American Society for Healthcare Risk Managers recognized the needle/syringe reuse problem and advised, "Attention needs to be kept on this issue through the JCAHO infection advisory panel, particularly as it relates to clinics and doctors' offices."

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) reported plans to raise the awareness of their surveyors about reuse of "single use" devices on more than one patient, including needles and syringes. JCAHO reported that the "whole issue of single use devices" is a problematic matter. JCAHO reported that they have revamped their infection control standards and 1 standard to be posted in 2005, IC 4-10, will relate to infection control and address the matter of reuse of devices that are deemed disposable by the manufacturer.

Early in 2004, the CDC's Division of Healthcare Quality Promotion and the Division of Viral Hepatitis were developing proposed initiatives to address the problem of patient-to-patient transmission of blood-borne pathogens in health care settings. In late 2004, a representative from the CDC work group charged with infection control in ambulatory care settings shared with AANA the CDC's concern that despite their 2002 bulletin regarding reuse of needles and syringes on multiple patients, outbreaks of Hepatitis B and Hepatitis C attributed to syringe reuse continue. While discussing the issue, the representative noted, "The [AANA's] recommendations seem so intuitive, yet it is so difficult to reach groups who may provide patient care and who are not aware of the risks of reusing injection apparatus and contamination of multi-dose vials. We [CDC] will be addressing this topic again soon and will pass on this information to the working group."

In April 2005 the CDC sent the AANA a request for the work group to continue with an initial focus on injection safety. The CDC expressed a concern that in spite of publicized outbreaks of Hepatitis B and C, some unsafe injection practices, particularly the injection of residual medication left in a syringe that has already been used on another patient, continue during anesthesia care and are underreported.

Dr. Lester is a Certified Registered Nurse Anesthetist, past President of the American Association of Nurse Anesthetists, and a member of the APSF Board of Directors and Editorial Board.

## **Safety Implications of JCAHO Standards Raise Concerns**

### by Robert S. Weller, MD

Patient safety is an issue that has received widespread national attention following the Institute of Medicine's (IOM) report in 1999: *To Err is Human: Building a Safer Health System,* in which the risk of patient harm from medical errors was identified.<sup>1</sup> Included in this report was Recommendation 8.2: "Health care organizations should implement proven medication safety practices."

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has included improving the safety of medication administration in its "National Patient Safety Goals" for both 2004 and 2005, and will be looking closely at compliance with Medication Administration Standards. Three specific line-items in the Patient Safety Goals are to remove concentrated electrolyte solutions from patient care units, to standardize and limit the number of drug concentrations available, and to identify and annually review a list of look-alike/soundalike drugs and take action to prevent errors involving the interchange of these drugs.

### JCAHO Standards Are Detailed and Sweeping

The actual JCAHO Medication Management Standards for January 2004 are far more detailed and sweeping than the "Goals," and directly impact anesthesia providers. The 2004 Standards include Medication Management Standard MM 4.20: "When an on-site, licensed pharmacy is available, only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short)." Intravenous admixture is defined as "the preparation of pharmaceutical product which requires the measured addition of a medication to a 50 ml or greater bag or bottle of IV fluid. It does not include the drawing-up of medications into a syringe, adding medication to a buretrol, or the assembly and activation of an IV system that does not involve the measurement of an additive. This Standard 4.20 specifies that preparation of such an IV admixture must be performed in a Class 100 environment (airborne >0.5 micron particulate count of <100 per cubic foot).

Where did this requirement originate? It appears that the JCAHO has adopted, word-forword, the compounding standard from the United States Pharmacopeia (USP), which went into effect in January 2004. Although the USP might not meet the definition of "proven medication safety practice" as recommended by the IOM report, the standard was subject to a period of national review and public comment and was promulgated with the requirement that it be enforced by state boards of pharmacy and subjected to survey by accrediting organizations. Of course, the pharmacy licensing boards only have jurisdiction over pharmacies and pharmacists, but the USP and JCAHO requirements resulting from this standard apply to practitioners of all types, in all health care settings where medications are compounded, including anesthesia providers in the operating room (OR).

### **USP Standard Has Long History**

To go back a step further, what was the background for this new USP Standard on medication compounding? For the past 3 decades, published cases or series of cases of infections in patients resulting from contaminated medications elevated the concern for the safety of compounded medications, including parenteral nutrition, cardioplegia, steroids, and analgesics. This history included 4 cases of fungal meningitis in North Carolina, one fatal, following epidural methylprednisolone injection contaminated at the same compounding pharmacy.<sup>2</sup> Additional cases of meningitis from epidural injection of contaminated steroids were reported in California and Michigan. A series of 11 patients receiving cardioplegia contaminated by Enterobacter was reported in 1986, with 8 patients rebleeding after surgery and 5 patients dying.3 Over this long history of safety concerns, particularly for drug contamination by compounding pharmacies, the American Society of Health-System Pharmacists (ASHP), the National Association of Boards of Pharmacy (NABP), and the USP have performed practice surveys and made recommendations to pharmacists and pharmacy technicians to try to improve medication safety. In 1991, the first national survey of compounding practices was performed by the ASHP,4 and that organization published voluntary practice guidelines in 1993. Another survey was performed in 1995, the guidelines were revised in 2000, and a third survey was performed in 2002. None of these surveys showed significant improvement or compliance with the voluntary (and expensive) ASHP guidelines, and therefore national standards were promulgated in 2004 (USP 797).

How does the United States Pharmacopeia develop such standards? The USP "is a nonprofit, nongovernmental, standard-setting organization that advances public health by ensuring the quality and consistency of medicines, promoting the safe and proper use of medications, and verifying ingredients in dietary supplements. These standards, which are recognized worldwide, are developed by a unique process of public involvement through the contributions of volunteers representing pharmacy, medicine, and other health care professions, as well as science, academia, government, the pharmaceutical industry, and consumer organizations." The details of the new, 2004, USP Standard (797) include its goal "to prevent harm and fatality to patients" as a result of microbial contamination, content errors, or ingredient errors in the compounding of sterile preparations. The definition of a "compounded sterile preparation" from USP is quite broad, and includes any of the following:

- a) Preparations prepared according to manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination.
- b) Preparations containing non-sterile ingredients or employing non-sterile components and devices that must be sterilized before administration.
- c) Biologics, diagnostics, drugs, nutrients, or radiopharmaceuticals that possess either of the 2 previous characteristics and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powder for injection, irrigations, metered sprays, and ophthalmic and otic preparations.

Obviously, nearly any manipulation of IV medications could expose the contents "to potential contamination," and other medical specialties such as nuclear medicine have expressed concern for the effect of these far-reaching regulations on their practice.<sup>5</sup>

The Standards identify various risk levels for medication compounding, and anesthesia providers only prepare sterile solutions from sterile ingredients, for immediate administration or administration over a limited number of (but <24) hours. This would likely qualify as a "low-risk" level for microbial contamination<sup>6</sup> in the professional judgment of pharmacy and anesthesiology practitioners, compared to preparation of IV admixtures for administration over several days ("medium risk"), or preparation from non-sterile components for later sterilization ("high risk"). Medication preparation by anesthesia providers also usually takes place in an OR with a required minimum of 15 air changes per hour (ACH), and usually by an individual

### **Institutional Guidelines May Reduce Contamination of I.V. Solutions**

### "JCAHO," From Preceding Page

wearing a mask and non-sterile gloves, but clearly not under a Class 100 hood. Having said this, anesthesia medication has been implicated (rarely) in the transmission of fungal and bacterial infection, most notably with the original propofol formulation with resultant sepsis and multiple organ failure.7 Heightened awareness of the risk,8,9 handling recommendations from the manufacturer, and reformulation of the solution have apparently reduced reports of patient infection, but other drugs have also been shown to be contaminated after anesthesia provider preparation, and 2 reported cases of hepatitis C transmission were linked to anesthesia medication. Still, these are rare reports, and the IOM report identified Anesthesiology and its Anesthesia Patient Safety Foundation (APSF) as a specialty that had dramatically improved patient safety over the last 20 years by collective action. Also, the American Society of Anesthesiologists specifically defines the anesthesiologist's responsibilities in perianesthetic care as including the preparation and check of (equipment and) drugs.

Clearly, although pharmacy organizations have been struggling with these medication safety issues for many years, this new JCAHO MM 4.20 Standard has caught anesthesia providers by surprise, and we have had little direction in determining its scope. In a recent list-serve query, the interpretation of MM 4.20 by academic health centers was quite variable. Many institutions have adopted a practice that requires pharmacy preparation of all IV admixtures, while others consider the OR to be a unique site where infusions and other IV admixtures may continue to be prepared by anesthesia providers.

The careful consideration of the application of JCAHO Standard MM 4.20 to anesthesia providers suggests there may be a real and dangerous safety trade-off that has not been part of the discussion to date. Once again, the intent of USP (797) and MM 4.20 is to improve medication safety both from the standpoint of reducing microbial contamination and reducing the potential for errors in measurement or dilution. Since anesthesia is commonly provided in the emergency setting which is an exclusion for pharmacy preparation of solutions, anesthesia providers will be placed in the position of preparing IV admixtures only in crisis situations. The risk of measurement or contamination error is likely to be *increased* by lack of familiarity and experience previously gained by compounding such solutions on a daily basis. The emergency situation with a critically ill patient is already a timepressured and risk-laden setting; this is the last place one would want to increase the potential for medication error.

It seems far more rational to adopt institutional practice guidelines that document safe practice and minimize the already low risk of microbial contamination of solutions, and allow anesthesia providers to continue to prepare all manner of medications in the OR environment. Such practices might include

- Mandatory use of gloves and mask when preparing IV admixtures from sterile ingredients in an OR.
- Annual training in aseptic medication preparation and written exam competence demonstration.
- Labeling of preparations with medication name, concentration, and time of preparation or expiration date (Standard MM 4.30).
- Discarding of preparations used in the OR within 24 hours, or when the patient leaves the OR or post-anesthesia care unit (PACU) and is transferred to another patient care area.

If adopting these simple safeguards could meet the requirements for safe compounding in a lowrisk situation for contamination, one might avoid the potential for increasing the risk of medication measurement error.

Dr. Weller is an Associate Professor and Director of Orthopaedic Anesthesia at Wake Forest University School of Medicine, Winston-Salem, NC.

#### References

- Kohn LT, Corrigan JM, Donaldson MS. To Err is Human: Building a Safer Health System. Institute of Medicine, Washington, DC: National Academy Press, 1999.
- Exophiala infection from contaminated injectable steroids prepared by a compounding pharmacy--United States, July-November 2002. MMWR Morb Mortal Wkly Rep 2002;51:1109-12.
- Hughes CF, Grant AF, Leckie BD, Baird DK. Cardioplegic solution: a contamination crisis. J Thorac Cardiovasc Surg 1986;91:296-302.
- Crawford SY, Narducci WA, Augustine SC. National survey of quality assurance activities for pharmacy-prepared sterile products in hospitals. *Am J Hosp Pharm* 1991;48:2398-413.
- Hung JC. USP general chapter <797> pharmaceutical compounding-sterile preparations. J Nucl Med 2004;45:20N,28N.
- Schubert A, Hyams KC, Longfield RN. Sterility of anesthetic multiple-dose vials after opening. *Anesthesiology* 1985;62:634-6.
- Postsurgical infections associated with an extrinsically contaminated intravenous anesthetic agent--California, Illinois, Maine, and Michigan, 1990. MMWR Morb Mortal Wkly Rep 1990;39:426-7, 433.
- Zacher AN, Zornow MH, Evans G. Drug contamination from opening glass ampules. *Anesthesiology* 1991;75:893-5.

### Web Survey on the Anesthesia Machine Pre-Use Check

Many significant developments have occurred since the Food and Drug Administration released the latest version of the Anesthesia Apparatus Checkout Recommendations in 1993. Anesthesia workstations that include electronics and software as an integral part of their design and feature different variations of semi-automated pre-use checks have begun to replace purely pneumatic anesthesia machines. Not all anesthesia ventilators use a bellows design anymore; there are now also piston ventilators. There are substantive differences in design, even within a given manufacturer's product line. Monitoring, whether integrated into an anesthesia workstation or as stand-alone units, is more prevalent. The new ASTM standard F-1850 for anesthesia workstations was released in 1998.

An anonymous survey is currently being conducted via the web to assess compliance with the 1993 Food and Drug Administration recommendation to perform a pre-use check of the anesthesia machine before every case. The survey questions are designed to obtain insight about the reasons for non-compliance and to seek patterns for non-compliance that could potentially be used to re-design the pre-use check to enhance compliance and effectiveness. This survey is for all who perform the anesthesia machine pre-use check, including anesthesia providers and anesthesia technicians.

We encourage active and candid participation of the APSF membership in the survey so that your input, concerns, and educational and training needs are adequately and accurately represented in the current survey.

The survey can be accessed and completed anonymously at the University of Florida's Virtual Anesthesia Machine website: http://www.vam.anest.ufl.edu/logincheck.html. To access the survey, one needs to register as a Virtual Anesthesia Machine user, which is free. After completion of the anonymous survey, you will be provided access to a preview of a free web simulation of the 1993 FDA Anesthesia Apparatus Checkout Recommendations, whose development is funded by the Anesthesia Patient Safety Foundation.

#### Sem Lampotang, PhD

Member, APSF Committee on Education and Training Project Director, Virtual Anesthesia Machine Professor of Anesthesiology

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### Letters to the Editor: Epidurals for Labor Are Labor Intensive

### To the Editor:

I read the recent APSF edition regarding fatigue and sleep deprivation with great interest as I myself struggled to stay awake one morning after call. It occurred to me that in my 20 years of practice that by far the greatest cause of fatigue, stress, and sleep deprivation to me has been the escalating and incessant demands of obstetrical anesthesia and specifically labor epidurals. The evolving standard of "every woman in labor deserves an epidural upon request" has enabled a small subgroup of patients to consume a disproportionately large amount of available anesthesia manpower. What was once a privilege of a few has become an entitlement to all and a tremendous drain on anesthesia resources.

I would estimate that labor epidurals represent less than 5% of patient volume and reimbursement to us nationwide but account for greater than 50% of the demand for after hour anesthesia services.

If we, as a specialty, are serious about addressing the problem of fatigue caused by sleep deprivation, the obvious place to start would be to re-evaluate our professional obligation to perform these underfunded and non-essential procedures after hours.

The standards set for us by hospital administrators, obstetricians, and our own ASA, regarding provision of labor epidural analgesia are not feasible in hospitals where anesthesia providers must work the next day following call. Total ablation of labor pain is a noble goal, but the cost to anesthesia providers in monetary and physical expenditure far exceeds the reimbursement. We should not have to "burn the candle at both ends" in order to appease one overly demanding group of patients by night and risk detriment to others who are entitled to our best efforts by day. Those of us in small groups who toil under these conditions could use some relief. I hope ASA and APSF policy makers are listening and can help in this regard.

Sincerely, TH Parker, Jr., MD Memorial Hospital Bainbridge, Georgia

> Improved APSF website **www.apsf.org**



### To the Editor:

I am writing in response to the topic of fatigue and the practice of anesthesiology. It has been said that common sense cannot be taught in schools. Fatigue and performance are negatively correlated, as we all know from the admonishments to get a good night's rest before exams. Don't patients deserve even more consideration? Overworked doctors and medical errors have been a flashpoint for discussion ever since I was a resident 18 years ago. And we are still doing research to find out how many medical errors are committed while fatigued.

Why do we need more studies to prove this? Do you really think that the true incidence of death or permanent injury will be discovered this way without exposing individuals, administrators, and hospitals to liability? I've learned all I need to know about vigilance as a truck driver. Vigilance is necessary to prevent accidents. Fatigue swallows up vigilance. But there's more. Fatigue depletes our cognitive power, diminishes our ability to retrieve critical information, and betrays our best intentions. We fail to see the obvious treatment and anesthetic options when fatigued. And even if we do, the energy to act on the knowledge of the best treatment plan is gone.

I find no reason for this continuing dialogue fatigue and what to do about it other than an economic one: it costs more to hire additional people. Yet the economic costs of decreased productivity from injury due to medical errors is in the billions of dollars. Until our leadership recognizes that this is money we pay for as a society, which eventually impacts on our health care costs and our compensation, this cognitive dissonance will continue. As a matter of conscience, I as an individual will manage my fatigue in a way that occurs commonly, if covertly. I will not relieve my colleagues for breaks on certain occasions, nor will I accept responsibility to conduct an anesthetic for their ASA class IV patient just to facilitate the OR schedule. I will take my time to answer my pages. I will not move any faster to do endoscopy cases just because someone has just decided to add on 3 more cases to an already full schedule. Without the element of risk, we can all be the good Samaritans that we imagined ourselves to be when we applied to medical school. With risk, everything changes. Let us stand up and fight to protect our patients instead of finding yet another way to bend over and accommodate an overly demanding system, because the next bending over may just break our backs.

Herb Lee, MD North Brunswick, NJ

### Anesthesia Technicians Are Professionals Too

#### To the Editor:

I would like to clarify for the readers of this publication who may have been offended by the comment made in response to an article in the Winter 2004-2005 issue of your newsletter, "Reader Calls for Professionalism." I quote, "I would like to think that we are all professionals and not just technicians." The definition of a technician is: a) of, relating to, or characteristic of a profession; b) engaged in one of the learned professions; c) characterized by or conforming to the technical or ethical standards of a profession.

Why would a reader feel the need to respond to the comment about "being a professional and not just a technician"? The APSF Newsletter is read by many anesthesia technicians who wish to enhance their knowledge in their profession of anesthesia. The need for anesthesia technicians in the field of anesthesia has grown tremendously, and as it continues to grow, the skills must continue to improve in order to provide the safest environment for the providers and the patients who rely on the professionals in the field of anesthesia. "Just a technician" implies that technicians are not a valuable asset to the anesthesia team. This was clearly not the intent of the writer. I would like to think that the reason for reading this publication is to further our knowledge in our profession, thereby eliminating the possibility of repetitive, career-ending mistakes, and gaining the knowledge needed to give patients the best and safest care possible while their lives are in our hands.

I will continue to increase my knowledge as an anesthesia technician by reading this publication and any other publication that may benefit my profession. After all, this is what a technician must do: to be a professional!

Daniel A. Clark, Cert. A.T. Jacksonville, FL

### Editor's Note:

We would like to apologize for any negative connotation to Mr. Clark and to the many professional anesthesia technicians who contribute their important skills and effort to patient care.

### **Letters to the Editor:**

### Monitoring Neuromuscular Silenced Alarm **Blockade Öften Overlooked** *Results in*

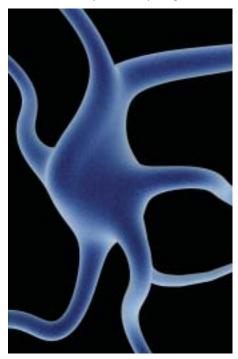
### To the Editor:

I am not a constant reader of the APSF Newsletter so perhaps I've missed the APSF's position on this topic; nevertheless, I think it represents a subject worthy of APSF attention. As a supposed "authority" on the clinical use of neuromuscular blocking agents (NMBA), I still come across clinicians who opine, "I haven't used a peripheral nerve stimulator (PNS) in 20 years and I see no reason to start now." On a recent visit to a well respected academic medical center, the anesthesiologist in charge of pediatric anesthesia told me that he never uses PNS units since they "don't work in kids."

While a recent editorial opinion (Anesthesiology 2003;98:1037-9) certainly does not support these ideas, I am unaware of any published clinical guidelines by organizations such as the APSF or the ASA on the subject. I think the time has come for these societies to clearly state that the administration of nondepolarizing relaxants in the absence of neuromuscular monitoring represents substandard care.

In a letter to a correspondent, I noted in part. . .

"I agree that there are only limited outcome data (Acta Anaesthesiol Scand 1997;41:1095-1103) to suggest that patients who arrive in the PACU with TOF ratios of 0.50, for example, have a significantly increased morbidity or mortality compared to indi-



viduals who have attained a TOF ratio > 0.80. To prove this thesis would require a rather massive project that is not likely to be funded. However, anesthesiology as a specialty has been lauded for the drop in anesthesia risk, which has been documented over the last 20 years. Improvements in monitoring have been cited as a major determinant of this perceived improvement in outcome. Nevertheless, there is little evidence-based data that clearly show that pulse oximetry or capnography in fact reduces overall morbidity. Yes, anecdotal reports abound, but the same can be said for the use of objective neuromuscular monitoring.

"When I was a resident (over 40 years ago) we did not have or routinely use electrocardiography, pulse oximetry, capnography, anesthetic agent monitors, or cerebral-function physiologic monitors. Nor did we miss them. Now I would feel naked without them. Do I use the TOF-Watch or the Datex M-NMT module in every case where nondepolarizing blocking drugs are administered? No. However, I sincerely believe that this monitoring modality should be routinely available to the anesthesiologist. My experience suggests that it is a great pedagogical tool. What it teaches is that clinical judgment is often wrong."

Aaron F. Kopman, MD New York, NY

### **Noise Pollution Obscures Pulse Ox Tone**

To the Editor:

While I agree that the pulse oximeter tone, alarms, and so forth should be audible and that the pulse oximeter tone should reflect the patient's oxygen saturation, it is often VERY difficult to hear these sounds over the 80-90 decibel sound pressure level of the music being blasted by the surgeons (and, unfortunately, now the anesthesia teams).

We need a limit on the volume of the "music" that is played in the OR. Often, when I am doing a case where I have had to place a temporary pacemaker (like a pacemaker-dependent patient having a mastectomy overlying the generator), many of the surgeons play music loudly enough that I have to turn it down myself.

It is only a matter of time before someone (the patient) gets hurt.

Marc A. Rozner, PhD, MD Houston, TX

# "Near-Miss"

### To the Editor:

I read with interest the deliberations regarding the use and abuse of alarms in the anesthetic environment in the Winter 2004-05 issue of the Newsletter. During my residency training I observed a near miss where a resident had silenced all monitoring alarms during a coronary artery bypass graft procedure. The resident disconnected the breathing circuit while the surgeon incised the sternum. He then forgot to reconnect it. It was only when I walked into the OR and asked why the pulse oximeter was reading 20% that he realized what had happened. Frantic efforts ensued and fortunately the patient came to no harm. But it was a salutary lesson for both of us.

I routinely use all monitors available. During my preoperative check of the anesthetic machine, I also check and activate all monitoring alarms. Some anesthetic machines and monitors are set automatically to default settings that are not appropriate. For example, monitors that have been in use recently in our hospital set the default lower oxygen saturation alarm to 88%. Following the recommendation of a colleague I set mine higher and now use 95% as the lower limit of oxygen saturation that I will accept. This gives early warning while there is still time to react.

In my practice the use of pulse oximeter tone is essential. I am continually amazed to see senior colleagues switch this off and rely on the single beat of the EKG monitor. Residents working in our team are routinely taught to use pulse oximeter tone at all times, and we stress all the information this provides: oxygen saturation, the presence of sinus rhythm or arrhythmias, and indication of cardiac arrest . We continually emphasize the importance of "tuning in their ears to the tone." Its absence or change should spark immediate investigation, particularly when they are away from the "anesthetic end of the table."

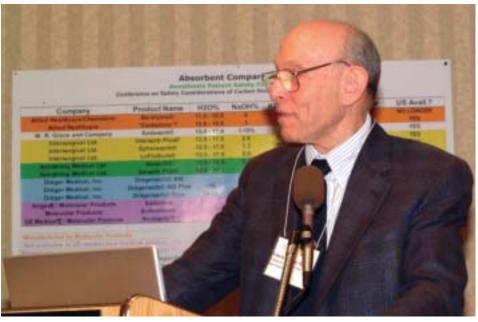
Robert N. Norton, BSc, MBChB, FRCA Kent, UK

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### More Photos From the Absorbent Conference (Article on Front Page)



Representatives from Absorbent Manufacturing join with APSF to explore safety considerations of absorbent dessication on April 27th, 2005 in Chicago, IL. Participants are (top row, left to right) Jeffrey Mack; Randall Ostroff, MD; Jonathan Deutsche, MD; Juergen-Ralf Lange; Christoph Manegold; Robert Stoelting, MD (APSF President); (bottom row, left to right) Michael Olympio, MD; Mike Holder; Dr. Michael Clarke; Dr. Ciarán Magee; Michael Mitton, CRNA.



Dr. Edmond I Eger, II, MD, addresses participants at Absorbent Conference.

## **MHAUS Reports**

### "MHAUS," From Page 31

Dr. Ganesh is Assistant Professor of Anesthesia at the Department of Anesthesiology and Critical Care Medicine, The Children's Hospital of Philadelphia, PA.

Dr. Saubermann is Frances F. Foldes Professor and Chairman of the Department of Anesthesiology, Albert Einstein College of Medicine, Montefiore Medical Center, NY.

Dr. Nicolson is Professor of Anesthesia, Associate Anesthesiologist-in-Chief and Director of the Division of Cardiothoracic Anesthesiology, Department of Anesthesiology and Critical Care Medicine, The Children's Hospital of Philadelphia, PA.

### Reference

1. Larach MG, Rosenberg H, Gronert GA, Allen GC. Hyperkalemic cardiac arrest during anesthesia in infants and children with occult myopathies. Clin Pediatr (Phila) 1997;36:9-16.

## Thanks to all of our readers, supporters and donors for making patient safety a high priority.



**Inside:** 

- Report on APSF Conference on Safety Concerns of Dessicated Carbon Dioxide Absorbents
- MHAUS Reports 3 Unique Cases of Hyperkalemic Cardiac Arrest
- Dear SIRS Explores Descending Bellows
- Syringe Reuse Transmits Infections
- JCAHO Standards Have Safety Implications

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