

NEWSLETTER

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If my spine surgery went fine, why can't I see? Postoperative Visual Loss and Informed Consent

This issue of the *APSF Newsletter* opens with a personal and tragic account of postoperative visual loss (POVL) in an anesthesiologist and follows with an update on POVL, a comprehensive review of informed consent, and a spine surgeon's perspective. We hope that these timely articles will increase awareness of POVL and encourage appropriate preoperative informed consent.

by Anthony D. Lehmer, MD

I'm a retired anesthesiologist. I was asked by Dr. Lorri Lee to write a brief article from the patient's perspective about posterior ischemic optic neuropathy (PION). I should know about it. It happened to me. I've been slow to write this. It's a rather painful subject.

Following my fifth back operation in September 2006 (a prone, redo 3-level lumbar fusion), I had so much swelling I was unable to open my eyes at all until about noon the next day. I at first thought I had Lacri-lube in my right upper eye, but soon became aware of the pulsating colors of scintillating scotomata in the upper 80% of the field of my right eye. (It was interesting in that, at least in the lower portion of the affected area, I could see through the flashing colors.) Having given a lecture on PION, I was pretty sure what the problem was. I called the surgeon's office and somehow impressed upon them that I needed to see an ophthalmologist right away. Fundoscopic exam was normal. Over the next 3 to 4 days, the scintillations diminished and were gradually replaced by gray with some improvement of the field cut to about 70%. I've been followed by a neuro-ophthalmologist with minimal improvement. Pallor in the infero-medial right optic disc was first noted on day 20, confirming the diagnosis of PION and ruling out anterior ischemic optic neuropathy (AION). I can still read normally, albeit a little bit slower, and my binocular vision is intact so I can drive; this doesn't affect daily life too much. I'm told my left eye is not quite normal, but I can't tell that because I have nothing to compare it to.

I practiced anesthesiology for 28 years, both in academic and private practice. I have not returned because I don't think someone with a significant visual field defect should be routinely responsible for intubating patients. I don't want to hurt somebody. I think I could probably intubate someone right now without difficulty, but the day that I didn't everyone in that room who knew of my problem or should have known would get to write a check. No one should want to be my partner.

I have no grudge against my surgeon or anesthesiologist (my former partner). They did a good job. My surgery lasted 7-1/2 hours with blood loss around 700 ml, less than the average of 9.8 hours and 2010 ml for PION cases. All of the recorded PION cases had either an anesthetic time >5 hours or a blood loss >1000 ml, so I was at risk on the basis of

time. But this was not a problem to be expected. In fact, it is a complication for which there is currently no way to monitor, no way to prevent, and no way to treat. I'm really quite fortunate, because 68% of the 83 cases (recorded at the time) woke up completely bilaterally blind and improved very little. Very probably, with another 20 or 30 minutes of surgery, I would have been in that 68%.

I knew about this complication. I had been to lectures about it, and I had lectured about it. I had discussed it at great length with my anesthesiologist. I will say that it was never mentioned by my surgeon, and when it happened, he tried to blame it on the anesthesiologist. Later, he told me he had seen one case as a fellow but thought it was a fluke. His office still reassures me this never happens. That's comforting. I'm

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In Memoriam:

The APSF wishes to express its deepest sympathy at the passing of **Dr. Ann S. Lofsky**.

Dr. Lofsky was a consultant to the APSF Executive Committee and a frequent contributor to this *Newsletter* on important topics, including hypoperfusion in the beach chair position, maternal cardiac arrest, and complications of cervical epidural blockade. She was a director emeritus of The Doctor's Company and a practicing anesthesiologist in Santa Monica, CA. Dr. Lofsky was board certified in both internal medicine and anesthesiology. She will be sorely missed by all who knew her. Our condolences are extended to Dr. Lofsky's family, friends, and colleagues at her untimely passing.

A Statement by the Executive Committee of the APSF

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



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POVL Victim Emphasizes Disclosure

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sure it occurs far less often in private practice because procedures there tend to go much faster than they do in teaching hospitals. But it does happen.

If this had occurred without my knowing of the possibility, I would feel far differently about it.

I'm very fortunate in that when I first entered private practice I had an older partner who pulled me aside and told me that since I had 4 kids I needed to get disability insurance that specified my occupation as anesthesiology. He told me it would be expensive and that I should never complain and always pay the premiums. Without that advice, my family would be in big trouble. The amount I receive is far less than what I was making and I still have 2 kids in college, so things are a bit tough around here. The Texas Medical Association, of which I had been a member for many years, refused me for medical insurance and that has become an ongoing problem.

I was at the top of my game when this occurred. The back problem now seems to have been solved, but what else do you do when you're a fully trained clinical anesthesiologist and can't practice anesthesiology at age 58? Pain medicine is an obvious option but that frequently involves a lot of bending over and the lifting and turning of patients. I really don't want to do another residency. There are general medicine things out there and I had hoped some administrative positions. But potential employers and even some of your former colleagues look at you like you are some sort of malingeringer when you tell them this story! So far, the only thing I've found is a small job examining military recruits.

This complication is a devastating one for patients and their families, even when it does not result in complete blindness. Disclosure *on every case* needs to be done not only by the anesthesia team, but also by the surgeon. An issue of this magnitude has to be presented well ahead of time in order to be properly understood, and the surgeon is the only one who has that opportunity. In addition, this is the only way it will be understood as a complication of positioning rather than an *anesthetic* complication.

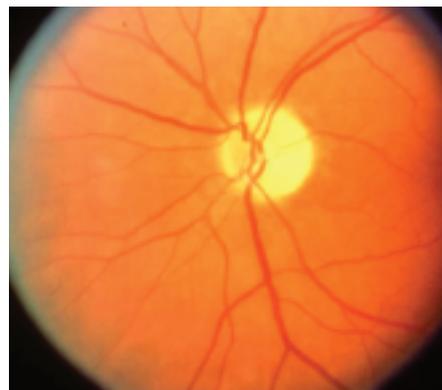
Dr. Anthony D. Lehner, MD, was a practicing anesthesiologist in Dallas, TX.

Solutions to POVL Mystery Requires Research

by Lorri A. Lee, MD

Postoperative visual loss (POVL) has received heightened attention in the anesthesiology, ophthalmology, and spine literature for almost 10 years now. We have made significant progress in disseminating the knowledge to the anesthesiology community regarding the different types of injuries to the visual system that can occur perioperatively, such as central retinal artery occlusion (CRAO), ischemic optic neuropathy (ION), and cortical blindness. Data from the ASA POVL Registry have clearly demonstrated that ION, the most common diagnosis in our database, has a distinct perioperative profile from that of CRAO patients. ION occurred with patients' heads suspended in Mayfield pins without globe compression, was commonly bilateral, and was associated with large blood loss (median 2.0 liters) and long anesthetic/operative times (≥ 6 hours anesthetic duration).¹ These associated features of ION are consistent with an injury caused by physiologic perturbations in susceptible patients, rather than direct trauma, as can occur with CRAO. The vast majority of patients in the ASA POVL Registry who developed ION were relatively healthy (ASA 1-2), and it has been reported in patients as young as 10 and 13 years of age after spine surgery.^{2,3} These findings suggest that any patient may be susceptible to developing this devastating perioperative complication, regardless of age or health status. Whether or not these patients who develop ION perioperatively have atypical physiology or vascular anatomy of their optic nerves remains unknown.

Though we now have a few more pieces of the puzzle of the etiology of ION, solving this mystery will require significantly more research in one or more directions such as 1) clinical multicenter retrospective case control studies or prospective multicen-



Ischemic Optic Neuropathy (late exam with optic nerve pallor) (Photo courtesy of Dr. Sohan S. Hayreh, University of Iowa)

ter observational studies; 2) development of an animal model for ION utilizing physiologic perturbations to create an injury of the optic nerve; 3) development of a reliable intraoperative optic nerve function monitor; and 4) studies of patients who have developed ION after spine surgery to determine if their physiology or anatomy is unique.

Until there is definitive evidence on the etiology and prevention of ION, the ASA Task Force on Perioperative Blindness has issued a Practice Advisory for Perioperative Visual Loss Associated with Spine Surgery with the following recommendations for major spine surgery cases:

1. consider consenting patients for the risk of POVL
2. use indwelling arterial catheters to monitor blood pressure, and consider use of a central venous catheter
3. use colloids along with crystalloids for volume replacement
4. position the head so that it is equal or above the level of the heart
5. consider staging procedures.⁴

Because of the significant variability in the blood pressure and transfusion management in patients who develop ION, no recommendations could be made for these areas.

Dr. Lee is Director of the ASA Postoperative Visual Loss Registry, Associate Editor of this Newsletter, and Associate Professor of Anesthesiology at the University of Washington, Seattle, WA.

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Informed Consent Requires Active Communication

by Colleen E. O'Leary, MD, and
Regina S. McGraw, RN, JD

The concept of informed consent is rooted in the fundamental ethical principle of the right of self-determination. This principle recognizes that patients are autonomous; that is, that they are independent agents with the capacity to make decisions regarding their well-being without coercion from others. The need to respect an individual's autonomy stems from the work of the 18th-century philosopher Immanuel Kant, but the medical-legal concept of informed consent was first introduced by 3 court cases in the mid 20th century. *Salgo v. Trustees of Leland Stanford Hospital* (Cal.App.2d 560, 317 P.2d 170 [Sup. Ct. Appl.]), in 1957, determined that the physician is required to explain the risks, benefits, and alternatives of a proposed procedure to a patient. *Natanson v. Kline* (186 Kan. 393.350 P.2d 1093), in 1960, further specified what information should be disclosed to a patient and introduced the "professional practice standard." This standard requires that a physician disclose to a patient what other physicians in the community would disclose under similar circumstances. In 1972, *Canterbury v. Spence* (464 F.2d 772 D.C. Cir.) introduced the "reasonable person standard" which requires disclosure of information that a reasonable patient would consider important in making an informed decision.¹

The Centers for Medicare & Medicaid Services (CMS), through their Conditions of Participation (CoP), which health care organizations must meet to participate in the Medicare and Medicaid programs, address the issue of informed consent. CMS grants "deemed status" to hospitals accredited by organizations they recognize such as the Joint Commission, ensuring that hospitals meet or exceed the CoPs. In a memo to State Survey Agency Directors dated April 13, 2007, the *Center for Medicaid and State Operations/Survey and Certification Group* announced revisions to the Hospital Interpretive Guidelines for informed decision making and informed consent. In the Patients' Rights CoP, (42 CFR §482.13(b)(2)), the interpretive guidelines state

Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent.

In the Surgical Services CoP (42 CFR 482.51 (b)(2)), the interpretive guidelines state

The primary purpose of the informed consent process for surgical services is to ensure that the patient, or the patient's representative, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this infor-

mation would include potential short and longer term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient's medical record, prior to surgery, except in the case of emergency surgery.

The interpretive guidelines further state

It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.

Securing a patient's consent for medical treatment is a process requiring effective communication between doctor and patient. Increasing numbers of patients view the doctor-patient relationship as a partnership and expect to be actively engaged in the decision-making processes governing their health care.

There are several elements intrinsic to the informed consent process:

Competence and Capacity

A detailed discussion of the terms *competence* and *capacity* is beyond the scope of this article. The term *competence* refers to a patient's legal authority to make decisions.

Adult patients, generally considered patients who are 18 or older, are presumed legally competent to make health care decisions unless otherwise determined by a court. Consent to treat a minor must be given by a parent or legal guardian unless state law recognizes certain conditions that may qualify as an exception to the general requirement for parental or guardian consent. For example, depending upon the state law, minors may be legally authorized to consent to their own health care if the patient is a parent; is pregnant and consenting for prenatal care; is married; is otherwise emancipated; or is in the active military.

"Capacity" refers to a determination made by medical professionals that a patient has the ability to make a specific decision at a specific time. To have capacity, patients must have the ability to understand and reason about their medical conditions, and to appreciate the indications, risks, benefits, and alternatives to proposed treatments. It is the physician's responsibility to determine if a patient lacks capacity to a reasonable degree of medical certainty. If a patient lacks capacity, consent must be obtained from an authorized decision maker, unless an emergency

or other exception applies. State law will govern who will be considered a legally authorized surrogate decision maker. For example, depending on the laws, this person may be a designated health care proxy, spouse, or an adult next-of-kin.

Consider the following example: a healthy adult patient who presents for elective surgery is competent and has capacity to consent for a surgical procedure. The same patient has an unexpected outcome, is in the intensive care unit, intubated and sedated, and requires a second operation. The patient will now not have capacity to consent for the second surgery, requiring the consent discussion to occur between the surgeon and the patient's authorized decision maker.

Disclosure of Information

Obtaining informed consent requires active communication between physician and patient. The communication process is an ethical obligation of the practice of medicine and a legal requirement per statute and case law in all 50 States.² The goal is to provide the patient with sufficient information to allow him or her to understand the nature of the medical problem; the indications for treatment; the material risks, benefits, and alternatives to treatment; and the consequences of refusing treatment. It is only then that the patient can make an informed choice with respect to suggested therapy. The informed consent discussion should allow a meaningful opportunity to have questions considered and answered.

What constitutes "sufficient information"? Most states use a "reasonable person" standard (see above), although there are some that rely on a "professional practice" standard. The informed consent discussion should focus on the indications for the proposed treatment, a description of the procedure in terms a layperson can understand, and an explanation of available alternatives. A frank disclosure of material risks of the recommended and alternative treatments is important. Material risks are those that a reasonable person would want to be made aware of before deciding to undergo or reject the recommended therapy. Material risks include those that occur commonly, but have little long-term consequence, as well as those that are rare but may result in severe, long-term morbidity or mortality. A recent informal survey of both private and academic institutions across the country revealed that the following "common" risks of general anesthesia are frequently disclosed: possible oral or dental damage, sore throat, hoarseness, postoperative nausea and vomiting, drowsiness, and urinary retention. Disclosure of more severe risks includes possible awareness, postoperative visual loss, aspiration, negative pressure pulmonary edema, organ failure, malignant hyperthermia, drug reactions, and the risk of failure to recover from the anesthetic, coma, or death. For regional anesthetics, common risks often

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Standardized Consent Process May Be Useful

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disclosed encompass prolonged numbness, “spinal headache,” backache, and failure of the regional technique. Less common but severe risks frequently discussed include bleeding, infection, nerve damage, persistent weakness or numbness, seizures, coma, and death.

Introduction of uncommon, but potentially devastating risks in the holding area, immediately preoperatively, is suboptimal for patients and uncomfortable for anesthesia professionals. This is especially problematic if their surgical colleagues do not habitually disclose specific risks that are known, uncommon, but significant sequelae of certain types of surgeries. Consider the risk of postoperative visual loss that has been associated with major reconstructive spine surgery, cardiac surgery, and extensive ENT procedures. It is conceivable that patients presented with the possibility of sustaining permanent visual impairment for the first time immediately prior to surgery may wish to reconsider or delay their decision to proceed with the proposed treatment. A better approach may be utilization of a standardized, institutional consent process developed by the surgical and anesthesia professionals who routinely care for these patients.

In addition to discussion of risks, benefits, and alternatives, some states require disclosure of the identity of all persons reasonably anticipated to be involved in the patient’s anesthetic care. Absent a written informed consent document naming all of the members of the anesthesiology department, this may prove to be problematic.

Practitioner’s Personal Recommendation

An important part of the informed consent process is offering the patient one’s professional opinion of the best options given the skill set of those providing the anesthesia, knowledge of the patient’s comorbidities, knowledge of the patient’s comorbidities, and the surgeon’s preferences. Important to this part of the discussion is an explanation of the pros and cons of the recommended technique as well as the back-up approach. It is important to appreciate the differences between persuasion, manipulation, and coercion in presenting this information to the patient.

Autonomous Authorization

Following a discussion of indications for the therapy, disclosure of material risks, benefits, and alternatives, and having questions answered, the patient is in a position to make an informed decision. The patient’s authorization to proceed with a proposed course of treatment is an expression of his/her right of self-determination and is the basis for informed consent.

Documentation

It is important to record the informed consent process in the medical record. Many organizations are adopting a separate, written informed consent document for administration of anesthesia. Some states require this, but there are other reasons to consider using this approach: common risks of all techniques can be clearly detailed; patient-specific risks can be

added in longhand; the patient and a witness sign the form; and it allows efficient documentation of the informed consent process for the growing number of patients who require anesthesia for a non-surgical procedure. Other organizations rely on the surgical consent form to document consent to anesthesia. This practice is problematic as the consent document may be completed in the surgeon’s office before the patient has an opportunity to talk with an anesthesiologist or nurse anesthetist; reliance on the surgeon to conduct an informed consent discussion for anesthesia presumes that they are as competent as an anesthesia professional to do this. Informed consent for anesthesia should be provided by those who are competent to do so. This important task pertains to a unique scope of practice and should not be delegated to those lacking this specialized knowledge and training.

Dr. O’Leary is an Associate Professor of Anesthesiology, Vice Chair for Clinical Affairs, and Director of Preoperative Services at SUNY Upstate Medical University, Syracuse, New York. Ms. McGraw is Associate Counsel at SUNY Upstate Medical University, Syracuse, New York.

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Spine Surgeons Striving to Increase POVl Awareness

by Jens Chapman, MD

Without doubt, the subjects of posterior ischemic optic neuropathy (PION), specifically, and perioperative blindness, in general, remain particularly bitter and challenging aspects of surgical care for all parties involved. Despite best efforts by many dedicated researchers there continues to be a lack of understanding of the true incidence of this potentially devastating event, with many of its pathophysiologic causes and potential for intraoperative monitoring unclear. Sadly, prevention efforts for PION and actual treatment remain at least equally as elusive to date. As far as we now know, major reconstructive spine surgery is one of the subspecialties more prevalently affected by perioperative visual loss (POVL), with magnitude and duration of surgery as well as positioning identified as potential contributing factors.

In this context, preoperative counseling of patients achieves a higher relevance than might usually be considered for adverse occurrences considered exceedingly rare by many surgeons. Similar to other

well-recognized devastating perioperative events, such as death, paralysis, and stroke, blindness, due to its potential impact on patients’ lives, should receive equal recognition in discussions with patients prior to engaging in elective procedures. Of course this discussion is difficult in many ways, since the topic of blindness especially strikes many patients entirely unprepared as they contemplate a procedure such as elective spine surgery. With no firm footing as to data on incidence and clear prevention strategies available to clinicians, entering this area of discussion is undoubtedly uncomfortable for many of us surgeons. As we strive for excellence in all aspects of health care delivery and are often challenged to present complex clinical information pertinent to specific conditions to patients in a meaningful condensed fashion, the added discussion of such extraneous sounding events as POVl may sound like an unwanted distraction from our essential mission. However, having personally been involved in the care of patients who have experienced POVl for unknown reasons, there is little doubt that a clear preoperative discussion of this

entity helps set the stage for a continued, productive physician-patient interaction in the unlikely case of its actual occurrence. As devastated as patients, their families, and all affected care providers are about unexpected significant POVl, the most meaningful care under such circumstances can be provided in an atmosphere of trust and open communication between these affected parties. As spine surgeons, we are striving to increase awareness about POVl through several of our professional societies. I personally view preoperative consenting with inclusion of perioperative blindness as a first step to raising disease awareness as well as diagnosis and treatment. Through more transparent documentation, we all can hope to make headway on the physiology, prevention, monitoring, and eventual treatment of these conditions.

Dr. Chapman is Professor and Director, Spine Service, and holder of the Hans Jöerg Wyss Endowed Chair at the University of Washington, Seattle, WA.

New Guidelines Available for Pre-Anesthesia Checkout

by Jeffrey M. Feldman, MD, MSE; Michael A. Olympio, MD; Donald Martin, MD; Adam Striker, MD

While chatting with a patient about to undergo a laparoscopic cholecystectomy, you administer an induction dose of propofol and an intubating dose of vecuronium. The patient loses consciousness and spontaneous respiration ceases. You adjust the mask on the patient’s face to establish a secure fit and squeeze the reservoir bag, only to find that you are unable to deliver a positive pressure breath. A quick visual inspection of the breathing circuit does not reveal the cause of the problem. Can you reliably ventilate this patient before he becomes hypoxic? Is an alternative method of ventilation readily available and functioning? Is there a reliable source of oxygen? Furthermore, you are using a relatively new anesthesia machine that performs an automated checkout procedure. What functions of the anesthesia machine did the automated checkout actually evaluate? Did you perform a thorough check of the machine before use that could have detected the source of this problem?

Failure to check anesthesia equipment prior to use can lead to patient injury or “near misses.”¹ Checking equipment has also been associated with a decreased risk of severe postoperative morbidity and mortality.² Indeed, a pre-use anesthesia apparatus checkout recommendation (AACR) was developed many years ago and widely accepted as an important step in the process of preparing to deliver anesthesia care.³ Despite the accepted importance of the 1993 AACR, available evidence suggests that it is not well understood and not reliably utilized by anesthesia providers.^{4,5} Furthermore, anesthesia delivery systems have evolved to the point that one checkout procedure is not broadly applicable to all anesthesia delivery systems currently on the market. For these reasons, a new approach to the pre-use AACR has been developed. The primary goals of this new approach are to have a procedure that is applicable to all anesthesia delivery systems, and one that will be reliably performed.

The effort to revise the AACR was initiated by the Committee on Equipment and Facilities at the 2003 annual ASA meeting after recognizing that the 1993 AACR did not apply to modern anesthesia delivery systems. A task force was established consisting of representatives from major anesthesia delivery system manufacturers, the American Association of Nurse Anesthetists (AANA), The American Society of Anesthesia Technicians and Technologists (ASATT), and the ASA. The task force met for the first time at the 2004 ASA meeting while working continuously via e-mail since 2003. The result of this process is a document entitled “Recommendations for Pre-Anesthesia Checkout Procedures (2008)” and a growing library of checklists for checking individual anesthesia delivery systems. This information is available on the ASA website in the Clinical Information section (<http://www.asahq.org/clinical/fda.htm>).

TABLE 1	
Recommended Essential Steps in a Pre-Anesthesia Checkout Procedure	
TO BE COMPLETED DAILY, OR AFTER A MACHINE IS MOVED OR VAPORIZERS CHANGED	
ITEM TO BE COMPLETED	RESPONSIBLE PARTY
Item #1: Verify Auxiliary Oxygen Cylinder and Manual Ventilation Device (Ambu Bag) are Available & Functioning.	Provider and Tech
Item #2: Verify patient suction is adequate to clear the airway.	Provider and Tech
Item #3: Turn on anesthesia delivery system and confirm that ac power is available.	Provider or Tech
Item #4: Verify availability of required monitors, including alarms.	Provider or Tech
Item #5: Verify that pressure is adequate on the spare oxygen cylinder mounted on the anesthesia machine.	Provider and Tech
Item #6: Verify that the piped gas pressures are ≥ 50 psig.	Provider and Tech
Item #7: Verify that vaporizers are adequately filled and, if applicable, that the filler ports are tightly closed.	Provider or Tech
Item #8: Verify that there are no leaks in the gas supply lines between the flowmeters and the common gas outlet.	Provider or Tech
Item #9: Test scavenging system function.	Provider or Tech
Item #10: Calibrate, or verify calibration of, the oxygen monitor and check the low oxygen alarm.	Provider or Tech
Item #11: Verify carbon dioxide absorbent is fresh and not exhausted.	Provider or Tech
Item #12: Perform breathing system pressure and leak testing.	Provider and Tech
Item #13: Verify that gas flows properly through the breathing circuit during both inspiration and exhalation.	Provider and Tech
Item #14: Document completion of checkout procedures.	Provider and Tech
Item #15: Confirm ventilator settings and evaluate readiness to deliver anesthesia care. (ANESTHESIA TIME OUT)	Provider

The 2008 AACR recommends that 15 separate items be checked or verified at the beginning of each day, or whenever a machine is moved, serviced, or the vaporizers changed (Table 1). Eight of these items should be checked prior to each procedure (Table 2). Some of these steps may be part of an automated checkout process on many machines. Following these

checklists will typically require <5 minutes at the beginning of the day, and <2 minutes between cases, but will provide you with the confidence that the machine will be able to provide all essential life support functions before you begin a case.

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Taskforce Recognizes Complexity of Checkout

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Early in the process of developing the new recommendations, the task force recognized that a single checkout recommendation could not be applicable to all modern anesthesia delivery systems. Not only does equipment design differ, but the automated checkout procedures built into many modern systems do not check all of the items that require attention, and vary from machine to machine. As a result, the task force has developed a guideline which describes the items that should be checked prior to use, rather than how each item should be checked. Actual checklists for everyday use will be based upon the guideline, but tailored to the equipment and resources available at a specific anesthetizing location. As a complement to the guideline, reference checklists are being developed for use by practitioners and departments interested in revising their checkout procedures. As new anesthesia delivery systems are adopted, revised checkout procedures will be required as the traditional AACR does not apply to modern equipment.

The task force also recognized that complexity is an obstacle to completing the checkout procedure. Therefore, the group worked hard to differentiate the items that must be checked by a clinician, from those items that could be checked by appropriately trained anesthesia technicians or clinical engineers. Departments that have skilled technician and engineering support may be able to develop checkout procedures that utilize these individuals, thereby reducing the time required from clinicians and increasing compliance with checkout procedures. The guidelines indicate which items could be checked by a technician alone or in conjunction with the anesthesia provider. Notwithstanding the role of the technician, the guidelines emphasize, however, that the ultimate responsibility for insuring that equipment functions properly lies with the anesthesia provider.

The Task Force further realized a need to emphasize requirements for safe delivery of anesthesia care, and listed these at the beginning of the recommendations. These requirements are the underlying rationale for the guideline, which specifies what should be checked prior to administering anesthesia. The requirements are

- Reliable delivery of oxygen at any appropriate concentration up to 100%.
- Reliable means of positive pressure ventilation.
- Backup ventilation equipment available and functioning.
- Controlled release of positive pressure in the breathing circuit.
- Anesthesia vapor delivery (if intended as part of the anesthetic plan).
- Adequate suction.
- Means to conform to standards for patient monitoring.

The new guidelines for Pre-Anesthesia Checkout were approved in the Spring of 2007 by the ASA leadership as a work product of the Committee on Equipment and Facilities. Since that time, the ASATT, the AANA, and The American Academy of Anesthesia Assistants (AAAA) have endorsed the document. The FDA had endorsed the 1993 recommendations that have been removed from their website, but the FDA has agreed to provide a link on their website to the ASA website where the new information will reside. The FDA has also endorsed the new guidelines as educational information.

Now that guidelines for checkout procedures have been developed, it is essential that clinicians be trained to utilize these procedures effectively. This is especially true when a new anesthesia delivery system design is put into service. New designs have significant differences from legacy systems.

The APSF has spearheaded the “Technology Training Initiative,” described on their website at http://www.apsf.org/initiatives/technology_training.msp, to promote critical training on new, sophisticated, or unfamiliar devices that can directly affect patient safety. The results and recommendations of their October 2007 “Workshop on Formal Training and Assessment before Using Advanced Medical Devices in the Operating Room” are published in the previous issue of the *APSF Newsletter*.

It remains to be proven if the goals of this effort will be realized. All anesthesia providers are encouraged to review the new guidelines and develop checkout procedures for use in their own practices. The library of checklists on the ASA website is intended to facilitate the process of developing local checkout procedures. We will continue to add to the library of sample checklists under the direction of Adam Striker from the University of Missouri, Kansas City. The ASA is urging the FDA to consider the recommendations in the guideline when evaluating automated self-tests as part of the 510K approval process of new anesthesia delivery systems. Our Task Force believes that providers who adopt this new approach will have taken all possible steps to eliminate the risk of patient injury due to anesthesia equipment malfunction.

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Contributors: (Individuals who have contributed in some fashion in the process of developing the new checkout guidelines): Abe Abramovitch (Datascope); Charles Biddle, CRNA, PhD; Robert Clark (Dräger Medical); Ann Culp, CRNA, MSN; Chad Driscoll, CRNA, MHS; Ann Graham, CRNA (FDA); Marc Jans (Dräger Medical); Michael Wilkening (Dräger Medical); William Norfleet, MD (FDA).

TABLE 2
Recommended Essential Steps in a Pre-Anesthesia Checkout Procedure

TO BE COMPLETED PRIOR TO EACH PROCEDURE	
SUBSET OF ITEMS IN THE DAILY CHECKLIST TO BE COMPLETED BETWEEN CASES	RESPONSIBLE PARTY
Item #2: Verify patient suction is adequate to clear the airway.	Provider and Tech
Item #4: Verify availability of required monitors, including alarms.	Provider or Tech
Item #7: Verify that vaporizers are adequately filled and if applicable that the filler ports are tightly closed.	Provider
Item #11: Verify carbon dioxide absorbent is not exhausted.	Provider or Tech
Item #12: Breathing system pressure and leak testing.	Provider and Tech
Item #13: Verify that gas flows properly through the breathing circuit during both inspiration and exhalation.	Provider and Tech
Item #14: Document completion of checkout procedures.	Provider and Tech
Item #15: Confirm ventilator settings and evaluate readiness to deliver anesthesia care. (ANESTHESIA TIME OUT)	Provider

OR Fire Occurs in Absence of Oxygen Enriched Environment: A Case Report

by Aleeta Somers-DeHaney, MD, and Joan Christie, MD

Abstract

Purpose: This case report and review describe a patient who sustained a burn in the operating room secondary to an alcohol-based skin preparation. The purpose of the report is to inform anesthesia professionals that such burns may occur at great distance from the airway and in the absence of supplemental oxygen as the oxidizer.

Clinical Features: An obese adult patient underwent a femoral distal bypass graft under general endotracheal anesthesia. The skin was prepared and later re-prepared with an alcohol-based solution that may have saturated skin folds over time producing vapors under the drapes. A sterno-like fire burned the patients' leg after the vapors were exposed to the electrocautery.

Conclusions: Alcohol prep solutions are frequently used in the operating room. Certain precautions must be observed to prevent fires. Room air, trapped alcohol vapors, plus electrocautery are sufficient to produce a fire. This case illustrates that such events may occur far from the airway or an exogenous oxygen source.

Introduction

The true incidence of operating room fires is unknown since there is no central reporting facility to track such data, and cases are underreported due to liability issues. The ECRI, an independent non-profit health services agency, estimates about 100 such fires occur in the US annually.¹ In June 2003 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published a Sentinel Event Alert on surgical fires.² Before the sentinel event alert all data regarding surgical fires were anecdotal and collected via multiple agencies with no single reporting mechanism.³

Anesthesia professionals are well aware of the possibility of operating room fires involving the airway, warming devices, and IV bags.⁴ The anesthesiology primary literature, texts, and presentations at professional meetings contain numerous reports and reviews of the phenomenon of airway fire.^{4,6} The risk of operating room fire from alcohol-based solutions has not been well-described in anesthesiology journals. Barker et al. reported experimental data and a case of a patient on supplemental oxygen who was burned from vaporized isopropyl alcohol prep in a "closed tent."⁷ In Barker's report the ignition source was electrocautery and the oxidizer was mask oxygen at 6 liters per minute. Although the fuel source was disputed in a subsequent letter to the editor by Bruley,⁸ there have been a few other reports of alco-

hol-based fires in the operating room.⁹ All of the reports thus far have involved fires in close proximity to an oxygen source near the airway.

We report the case of a patient undergoing a peripheral vascular procedure who sustained a 1% total body surface area burn after his skin was prepared with a 74% alcohol/iodophor liquid prep solution.

Case Report: Intraoperative Burn

An obese, adult patient was scheduled as an outpatient for unilateral femoral distal bypass. The patient was taken to the OR and anesthesia was induced with midazolam, propofol, succinylcholine, and rocuronium. His trachea was orally intubated and anesthesia was maintained with sevoflurane and 30% oxygen. After intubation, the patient's leg was prepared with the 74% alcohol-based prep solution. Midway through the case the skin was reprepared. The surgeon reported a heat sensation briefly during the case. About two-thirds into the procedure, the surgical drapes ignited under the patient's left knee. Flames were extinguished immediately. Two oval burn areas behind the left knee were noted. The surgeon was present, completed surgery, and applied silversulfadiazine cream and dressing. The patient's neuromuscular blockade was reversed and his trachea was extubated. He was taken to the PACU in stable condition.

Consultation with a burn specialist was obtained postoperatively. The wounds included a 2nd degree burn to the left posterior thigh, 3 x 3 cm deep to full thickness; and a 2nd degree burn to the left posterior popliteal fold, 4 x 1 cm. The consultation assessment was that the patient had a less than 1% total body surface flame burn to the left lower extremity. Conservative management with silver sulfadiazine dressing changes was recommended with burn clinic follow-up.

Discussion

Our search of the US Food and Drug Administration's (FDA) Manufacturer and User Device Experience (MAUDE) database, using the keywords *alcohol* and *fire* revealed that 25% of reports specifically associate alcohol-based solutions with surgical fires or patient burns. A recent closed claims anesthesiology report contrasted causes of burns prior to 1995 and subsequent to that date.⁴ The percentage of fires caused by cautery (excluding primary cautery burns) increased from about 12% to 19% over the study period. Thus, multiple data sources suggest that cautery fires and fires involving alcohol-based prep solutions are becoming more prevalent as a percentage of operating room fires. There are only a few reports in the anesthesiology literature of alcohol-based OR fires,⁷ and all occurred near the airway. The role of alcohol-based surgical prep solutions in operating room fires has been disputed.

Our case clearly illustrates that alcohol-based solutions can cause OR fires even in the absence of supplemental oxygen, and we report this case to inform anesthesia professionals and to underscore the importance of proper surgical prep in patient safety.

A combination of 3 factors involving alcohol or alcohol prep solutions can lead to fire or burns:

1. Solution may wick to the patient's hair and linens or pool on skin thus retarding drying time.
2. Drapes may be applied before the solution is completely dry and alcohol vapors may become trapped under surgical drapes.
3. Repreparation of an area increases the chance that the solution may pool and not thoroughly dry.

If these conditions occur, an electrocautery or other heat source may ignite the alcohol vapors. Both of these factors may have contributed to the fire in this case. The patient was obese, and solution may have pooled in skin folds or drape crease. Reprep of the skin may have exacerbated the pooling effect.

Previous cases of alcohol-based fire have all described an oxidizer in close proximity to the fuel and heat sources.^{10,11} The usual oxidizer described was supplemental oxygen administered via mask or nasal cannulae. Our patient was unusual in that although his trachea was intubated the surgical site was as far away as it could be from the airway. Thus the oxidizer was room air (21% oxygen).

This fire was not detected during the case, as the burning vapors did not result in visible ignition. The surgeon felt a transient flash of heat as the sole indicator of the vapor fire beneath the drapes. He interpreted the sensation as indicative of a pinhole in his glove allowing a slight cautery hand burn.

Manufacturer's instructions for the correct application of alcohol-based prep solutions have long warned about the flammability of the alcohol in solution and the need for adequate drying time. In October 1997, suppliers revised labeling to instruct users to prevent the solution from pooling, blot any excess solution, remove soaked drapes, and so forth.¹³ Suppliers require sales representatives to provide annual operating room in-service training to customers.

The ECRI has made the following recommendations for the use of alcohol-based prep solutions in the operating room:¹⁴

1. The manufacturer's instructions should be read and followed. Only skin preps and kits with clear and explicit instructions and prominent warnings should be purchased.

See "Fire," Next Page

ECRI Recommendations Decrease Risks

“Fire,” From Preceding Page

2. Surgical, emergency department, and all appropriate personnel should be alerted and made aware of the problem.
3. Alcohol based prep solution should be applied like paint; it should not be laid on in a thick, drippy, runny coating that could lead to excessive drying times.
4. The drapes should not be applied until after the prep has fully dried as shown by loss of shine of the film. This may take several minutes.
5. Liquid prep that has dripped away from the surgical site should be blotted with gauze sponges before it can soak into any absorbent material. Pooled prep solution should be wicked with gauze sponges instead of blotted or wiped so that the antimicrobial film is maintained on the skin.
6. If prep solution wicks into a material, staff must replace the material or allow sufficient time (possibly longer than 10 minutes) for the solution to dry before the drapes are applied.
7. If alcohol-based preps are used, ensure that solution does not soak into hair or linens. Sterile towels should be placed to absorb drips and runs and they should be removed before draping. Daubing of prep pooled on skin (e.g., umbilicus, cricoid notch) may be necessary.
8. Use incise drapes if possible. If the incise material does not adhere to the patient, the prep is likely still wet and the patient should be redraped once the prep is fully dry.

9. During surgery be aware of any sudden flash of heat. Such a flash of heat may indicate an occult alcohol fire. Search for smoldering materials and remove them.

We concur with the ECRI recommendations above. Anesthesiologists, nurse anesthetists, and anesthesiologist assistants are already informed and vigilant about heat sources and anesthetic gas oxidizers, including oxygen, particularly around the airway. In this unusual case, the oxidizer was room air, the fuel was alcohol vapor from the prep solution, and the fire was far from the airway. We wish to heighten awareness of the potential risk to patients from alcohol prep solutions and to stress the importance of strict adherence to the ECRI recommendations for the safe application of alcohol-based skin preparations.

Dr. Christie is an associate professor of anesthesiology at the University of South Florida College of Medicine in Tampa, FL.

Dr. Somers-DeHaney is a senior resident in anesthesiology at the University of Miami in Miami, FL.

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Letter to the Editor

Reader Examines Accident Related Traits

To the Editor:

As I pilot I’m interested that anesthesia is trying to apply aviation principles to accident prevention. The FAA has been collecting accident reports for 60 years now, and the same accidents are still happening no matter what has been tried.

A few years ago a study was done to look at what personality traits contributed to accidents, and from this a series of tests were developed to look for these traits in student pilots.

I actually talked to David Gaba about trying to do the same thing for anesthesia, but the Gulag got too busy to work on it. Table 1 outlines the traits.

Table 1. The Five Antidotes

Hazardous Thought	➔	Antidote
Anti-Authority		
“Don’t tell me.”	➔	“Follow the rules. They are usually right.”
Impulsivity		
“Do something—quickly!”	➔	“Not so fast. Think first.”
Invulnerability		
“It won’t happen to me.”	➔	“It <u>could</u> happen to me.”
Macho		
“I can do it.”	➔	“Taking chances is foolish.”
Resignation		
“What’s the use?”	➔	“I’m not helpless.”

There is a fine line between *macho* and *anti-authority*. About 80% of all accidents are anti-authority related.

It would be interesting to look at closed claims and see if this holds true for anesthesia. Since everyone is competing for residents, I doubt there would be support for psychological screening of residents.

I’m sure readers saw the recent article on the neurosurgery problems in Rhode Island. They seem to fall into the macho/anti-authority class.

Colin McKinley
Winston-Salem, NC

Dear SIRS

How Do Flow Sensors Work?

SAFETY
INFORMATION
RESPONSE
SYSTEM

Dear SIRS refers to the Safety Information Response System. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by 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 2004 issue.

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

Dear SIRS:

We have just installed new GE Aisys anesthesia machines that use the 7900 SmartVent®. This ventilator uses 2 breathing circuit flow sensors, which have a pressure sensor tube on each side of a small mylar flap. I understand how a pressure drop over a fixed resistance can be used to calculate flow, but this is a variable resistor because the flap opens as flow increases. So how does this thing work? In other words, how do they calculate flow given both a pressure variable and a variable resistance? ARRRGGH-HHHH!!!!

*James F. Szocik, MD
 University of Michigan*

In Response:

Dear Dr. Szocik,

Flow sensors are a critical monitoring and feedback-regulating component of modern anesthesia machine ventilators, and this type is common to many of the GE-Datex machines. Dräger Medical, Inc., and Datascope, Inc., on the other hand, utilize a different type of flow sensor (a hot-wire anemometer, e.g., in Fabius®, Apollo®, and Anestar® machines.) This question about the GE variety originally appeared in the

Society for Technology in Anesthesia (STA) listserv, with numerous responses from their membership. With their permission to reproduce this question, and to expand the understanding of flow sensor technologies, we asked the experts from GE Healthcare and Dräger Medical to enlighten us. I have included some additional questions for them to consider: How is the information used by the ventilator, with particular regard to the inspiratory versus expiratory sensor? Under what conditions has this technology failed, or is likely to fail?

*Michael A. Olympio, MD
 Chair, Committee on Technology*

In Response:

Dear Dr. Szocik,

Various technologies are used to measure airway gas flow and volume deliveries. These include pneumotachometers, hot wire anemometers, rotating vane spirometers, and ultrasound flowmeters. Each of these technologies offers different benefits and drawbacks depending on their underlying property used to detect flow.

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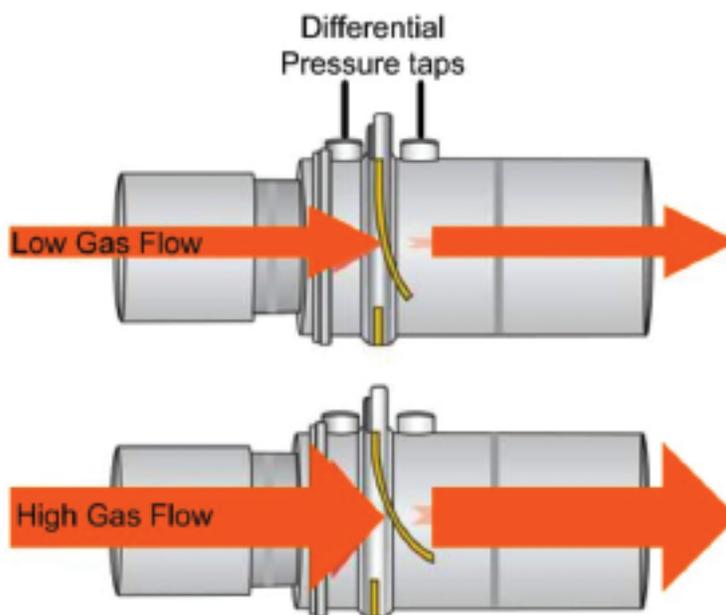


Figure 1. GE Healthcare flow sensor. In response to increasing gas flow, the flapper of the variable orifice opens more widely to decrease resistance to flow, thereby straightening the differential pressure vs. flow response.

Manufacturers Explain Flow Sensor Technology

“Dear SIRS,” From Preceding Page

A pneumotachometer uses a restrictor in the gas flow passage to create a pressure drop that can be sensed by a differential pressure transducer. (Note: It is the difference and not the pressure from each side of the orifice that is being measured.) Each output signal from the pressure transducer consistently represents a unique gas flow rate, and is calibrated to accurately report the measurement in gas flow rate. An orifice is a simple and inexpensive construction for a flow restrictor. The disadvantage of a fixed orifice is its non-linear relationship between the differential pressures and the gas flow rates. The size of the fixed orifice is a compromise between a tolerable flow resistance at high flow rates, and adequate obstruction to create detectable differential pressures at low flow rates. If the selection of orifice size favors the low flow sensitivity, the pressure transducer runs out of measurement range at high flows. If the orifice size favors high flow range, the pressure transducer would not receive detectable signal for measurement sensitivity at the low flow rates. The necessary compromise in measurement range also affects computation of patient tidal and minute volumes, which are derived by integrating gas flows in the airway. The demand for large flow range measurement is needed to cater to size of patients. Fixed orifice sensors require separate flow sensors for adult and pediatric patients. The variable orifice flow sensor elegantly solves this problem, allowing a single sensor for adults, pediatric patients, high flows, and low flows.

The 7900 Smartvent® in the Aisys®, Avance®, Aespire®, and Aestiva® Anesthesia System uses a single restrictor comprised of a variable orifice to measure gas flows in both pediatric and adult patients. Variable orifice flow sensing technology dates back to the 1930s, but its practical adoption as airway flow

measures began many decades later with a flap that opens with increase gas flows (Figure 1). The 7900 Smartvent® flow sensors are available in a Mylar or stainless steel material. The former can be used in Magnetic Resonance Imaging (MRI) suites in conjunction with the Aestiva® MRI anesthesia system. The stainless steel flow sensors are autoclavable, and are designed for long-term use.

At very low flows, the flap is in its natural state to form a small slit orifice. This small orifice allows an easily measurable differential pressure signal to be generated despite the low flow. As the gas flow increases, the flap opens more, reducing resistance to gas flow. At a given flow rate, the differential pressure across the deflected (more open) flap is lower than at its natural position. As in a fixed orifice, there is a one-to-one correspondence between each flow rate and the pressure drop that it creates. This allows the differential pressure measurement to be uniquely converted to the gas flow rate. Furthermore, the variable orifice straightens the pressure-flow characteristic to provide linear and uniform measurement sensitivity through its measured range.

While each individual variable orifice is unique and consistent, they differ slightly from transducer to transducer. To keep the tight specified accuracy, each transducer is individually calibrated in each direction of gas flow, and the calibrated table is electronically stored in the variable orifice connector. The 7900 Smartvent® “reads” the calibration table and converts the measured differential pressures across the variable orifice to the flow rates. The flow sensor is also corrected for variations in gas composition, altitude, and circuit pressures to provide accuracy in clinical use.

The 2 variable flow sensors provide many useful features to deliver and monitor patient ventilation.



Figure 2a. External view of the GE Healthcare Off-set flow sensor for use in moist airways gas passages.

Fresh gas flow to, and gas compression in, the Anesthesia Breathing System change the gas volume delivered by the ventilator flow valve to the patient. The 7900 Smartvent® uses the inspiratory flow sensor to measure the inspired tidal volume and compensate breath-to-breath the inspired tidal volume delivery to match the user setting. This flow sensor is also sensitive in detecting small flow rates, as low as 200 ml/min, at the start of a breathing effort to trigger a synchronized assisted or supported breath in spontaneously breathing patients, including neonates. In addition, the ventilator computes tidal and minute volumes from the flow measurement. They are used to detect low minute ventilation and apnea. Its ability to detect bidirectional flow is used to monitor unexpected flow reversal, such as caused by a stuck open inspiratory or expiratory check valve, in the Anesthesia Breathing System.

Tidal volumes and minute ventilation obtained from the expiratory flow sensor are used to detect and alarm on low minute ventilation and apnea. This flow sensor also acts as a safety check to constantly monitor the appropriate volume delivered by the ventilator, and alarms when the expired gas volume varies significantly from the setting. Such variations may be caused by leaks or valve or flow sensor issues. Moisture is an inherent by-product of carbon dioxide absorption in the circle breathing system, especially in low flow anesthesia practice. Moisture may cause small beads of water or a foggy appearance in the flow sensor, which does affect performance. Pooled water in the flow sensor or water in the sensing lines could result in false readings. The Off-set Flow Sensor (Figure 2a) is designed to address this issue by adding taper and grooves in the sensor housing to channel water away from the affected areas, as shown in Figure 2b. The Off-set flow sensor allows the use of

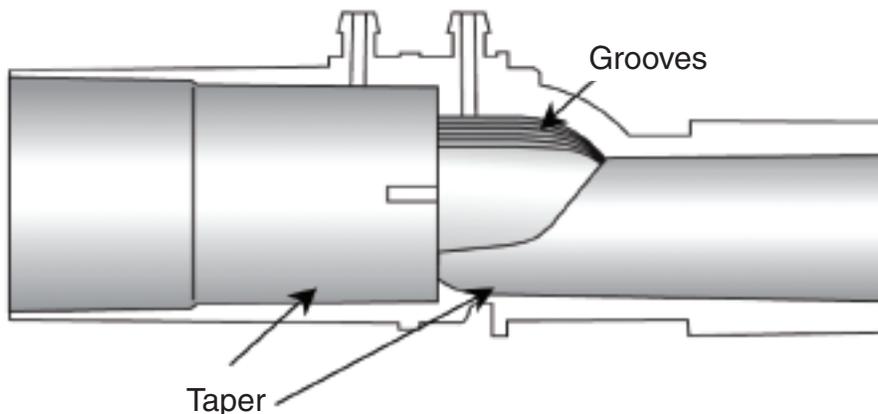


Figure 2b. Cut away view of Off-set flow sensor body showing the taper and grooves design.

See “Dear SIRS,” Next Page

Dear SIRS

Gas Measurements Affected By Water Vapor

“Dear SIRS,” From Preceding Page

the flow sensors in high humidity, without resorting to system heating.

We hope that this brief answers your question and highlights the practical and beneficial use of our dual breathing circuit flow sensor in patient ventilation during anesthesia.

*Robert Tham, PhD
Advanced Technology Group
GE Healthcare, Life Support Solutions*

*Michael Oberle
R&D Manager—Anesthesia Systems
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In Response:

Dear Dr. Szocik,

We thank the editor for the opportunity to respond to this general topic. As the technology for the instrumentation of our anesthesia systems and monitors has improved, our trust and reliance upon the data that the sensors provide has risen in relation. Drs. Szocik and Olympio make a valuable observation that we should understand the behaviors and limitations of the technology, otherwise we run the risk of misinterpreting the situation presented. The anesthesia machine, ventilator, or monitor relies upon the information that it receives from the sensor technologies employed.

The measurement of respiratory gases in anesthesia has to take into account not only the gas mixture, which changes during the procedure, but also changing airway pressures and humidity. Water vapor in the respiratory gases is an inevitable reality in the OR. Indeed, it is desirable to humidify and warm the fresh gas prior to it being delivered to the patient. In order to minimize the impact of water vapor on the breathing system and the respiratory gas measurement, Dräger Medical many years ago decided the best

approach was to maintain the water as vapor rather than allow it to condense out in the absorber system, which is typically the coldest part of the gas path. This removes the historical limitation for the use of low and minimal fresh gas flow techniques.

The hot-wire anemometer used by Dräger in the current range of anesthesia devices has the characteristic of being insensitive to water vapor and has a very low resistance and no moving parts. The sensor works by measuring the cooling effect of the gas passing over a thin, heated wire. The higher the cooling effect, the higher will be the flow of gas. In order to be accurate, the sensor needs to know the density of the gas, which is provided to the measurement system by the gas analysis data. This same technology is used internally in the GE Aisys® anesthesia machine for the measurement of fresh gas flow as well as in many other industries including aeronautics where the hot wire anemometer has become the standard for air speed measurement in aircraft.

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In Memoriam

In memory of Dr. Marc Balin (anonymous)
In memory of Louis S. Blancato, MD (Dr. and Mrs. Bernard V. Wetcler, MD)
In memory of Maurice Chait, MD (Texas Society of Anesthesiologists)
In memory of Bertram Watts Coffey, MD (American Society of Anesthesiologists)
In memory of Margie Frola, CRNA (Sharon Rose Johnson, MD)
In memory of Stephen D. Graham, MD (Texas Society of Anesthesiologists)
In memory of Laurie A. Noll, MD (The Coursin family)
In memory of Bonnie J. Slarsky (Jeffrey B. Cooper, PhD)
In memory of Dr. Richard Strausbaugh (Anesthesia Associates of York, PA)
In memory of Rex E. Thomas, MD (Texas Society of Anesthesiologists)
In memory of Leroy D. Vandam, MD (Dr. and Mrs. George Carter Bell)

Q & A

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

Q Dear Q&A,

Last year, the Executive Committee of the APSF considered whether or not it would be safe to re-use the syringe of medication within the syringe pump, if in fact the small-bore extension tubing was changed between patients. We did not know whether it would be possible for retrograde contamination to occur, if in fact the syringe was pressurized and the tubing was connected to a proximal intravenous port. Although there was variation in individual response, our opinion mostly, if not unanimously, opposed such practice. We knew that previous studies had demonstrated via Hemocult® testing that invisible blood could migrate many inches retrograde up free-flowing IV tubing, at least. Does your committee have any opinion or facts in this matter?

A Dear Executive Committee,

Your question generated numerous emphatic responses that are listed here:

I would never use IV sets or infusions from patient to patient regardless of extension tubing or type of pressurized pump.

I am strongly against the practice of using a syringe for more than one patient. There are the infectious disease issues, which include both the theoretical retrograde contamination with bacteria, viruses, and prions and also the issue of having the medication drawn out of a sterile vial and remaining in a syringe for longer periods than if it were freshly drawn. Additionally, there is also the concern that a drug labeling error (though less likely with propofol) could now affect more than one patient.

I would think that a "multiple use" practice would be a legal problem as well.

As a former hospital administrator, I can't imagine such a practice being defensible. Therefore I would avoid it.

Reuse of a syringe with change of tubing between patients is totally unacceptable,

although one type of tubing contains a one-way valve with a forward cracking pressure of approximately 100 mmHg and a reverse cracking pressure that is much, much higher. Nonetheless, reuse of syringes with a change of tubing between patients is totally unacceptable.

In my opinion, currently UN-controlled substances with potential for abuse might need internal control or at least internal audit capability. This is one more reason for not reusing a propofol syringe between patients, for example.

There is no possible justification for such practice, no matter how small the risk of cross-contamination.

I am in full agreement . . . absolutely no justification for re-using the syringe. Interestingly, I participate in providing anesthesia and medical leadership for surgical mission work (e.g., Guatemala) on a regular basis. We are always burdened with very limited resources, but would never support or condone such a practice.

I think providing opinion is helpful, but providing evidence is better. A short search of PubMed found several pertinent articles. A more detailed search would probably find more specific articles; however, the general consensus of these articles (from many countries and over many years) is that a tubing set should be used with only one patient. By extension, the suggested practice is wrong and very likely dangerous.

It seems that there is pretty uniform consensus against this. The professional societies should also be a resource, and here, for example, are relevant quotes from the AANA's infection control manual (available online at http://aana.com/resources.aspx?ucNavMenu_TSMMenuTargetID=51&ucNavMenu_TSMMenuTargetType=4&ucNavMenu_TSMMenuID=6&id=732):

Administration of Drugs and Solutions

The potential for infection and transmission of microorganisms exists during the administration of drug therapy. Instructions for preparation, storage, and

administration of all pharmaceutical agents provided by each manufacturer shall be read and followed. Drug administration by injection offers many opportunities for contamination. These include previously used needles, syringes, drug administration sets, intravenous tubing, and fluid containers.

#11. Do not reprocess for multiple use any intravenous fluids, tubing, or other intravascular infusions or connectors that are single-use disposable items. This includes transducers, tubing, and other items that make contact with the vascular system or other body compartments.

In our Clinical Engineering department we inspect syringe pumps for delivery accuracy. After multiple uses, we notice that the syringe integrity begins to degrade. This is manifested by the downstream occlusion pressure continuing to rise, secondary to increasing friction between plunger and barrel. We experienced some syringes causing false occlusion alarms during these tests. Such testing is performed using just water, and changing the fluid medium would undoubtedly have an impact. Many operators would not think the syringe is wearing out when it "looks" perfectly fine. You cannot determine the self-integrity of a multiple-used syringe unless you attach a pressure meter to it. Furthermore, fluid delivery rate can influence the friction; slower rates have more problems. These are just some technical things to consider if using a syringe multiple times.

Editor's Note:

Subsequent to the consideration of this question and the answers provided above, the highly publicized incident of actual cross-contamination in Nevada¹ made national headline news, and in February 2008 the U.S. Department of Health and Human Services Centers for Disease Control and Prevention released a Fact Sheet, "A Patient Safety Threat—Syringe Reuse," online

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Nevada Events Prompt Response

“Q&A,” From Preceding Page

at http://www.cdc.gov/ncidod/dhqp/PS_SyringeReuseFS.html, to patients who may have been exposed to multiple use vials/syringes/needles. That fact sheet, in addition to advising such patients, contains a link for health care providers:² http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html, regarding standard precautions for preventing transmission of infectious diseases, specifically including “Safe injection practices” under section IV.H. The precautions and practices state

Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.

The following comment was opined after revelation of the Nevada event:

I think it is correct but insufficient to condemn such a practice without acknowledgement of the factors that could lead to syringe re-use. Addressing the symptoms without trying to cure the underlying “disease” would be but a short-term solution. Thus, we must investigate, understand, and eliminate the factors that predispose one to the practice of unsafe medicine: as clinicians, we face severe production pressure and take “shortcuts” in the process of safe preparation of medication; we may give in to the financial importance that others, or we ourselves, place on speed and efficiency; or we may sincerely believe that we are preventing waste, thereby reducing the cost of medicine. An understanding of this complex environment may help to eliminate the root cause of such behaviors, which could then facilitate safer practices.

Dr. Olympio

- 1 Wells A, Harasiim P. Exposure Feared: 40,000 LV clinic patients urged to be tested for viruses. Syringe reuse at Endoscopy Center of Southern Nevada “common practice.” *Las Vegas Review-Journal*. Feb. 28, 2008.
- 2 Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings, June 2007.

Pros and Cons of Multiple Machine Types

Q Dear Q&A,

I am a private practice physician at a community hospital where the administration purchases and maintains our fleet of anesthesia machines. Several years ago they committed to replace all of our machines. Our understanding was that a single model of machine would be placed throughout the facility. Currently we have a blend of manufacturers and models, some of which will not be supported after next year. We are asking to expedite the purchase process at this time and make the fleet consistent within this facility. I have been asked to provide information justifying this move. Specifically, I was asked if there is an ASA standard (or equivalent) addressing the benefits of a single machine model within a facility. Or, asked another way, what are the drawbacks of having multiple types of anesthesia machines within a single group of users? Does such information exist or can you point me to any resources?

*Michael G. Royce, MD
Tulsa, OK*

A Dear Dr. Royce,

Thank you very much for your question to the Q&A column. We are unaware of any ASA standards or other recommendations regarding your situation, and, a similar question pertaining to an academic installation is also pertinent. Please allow us to categorize our responses to you.

Confusion. The range of currently available anesthesia delivery systems includes many different models and manufacturers, including machines for office-based practice, MRI, and Day Surgery centers. Having multiple models and manufacturers in a single operating room suite relies on the fact that each provider has been trained on, and maintains intimate familiarity with, a much larger spread of features, shortcomings, and quirks, than if a single anesthesia delivery system were deployed. Attention may be misdirected to the operation of the anes-

thesia machine and could have negative consequences for the patient.

Education. This immediately brings to mind the **Dear SIRS** article in the Winter 2004 *Newsletter*. Who will be the key individual or local “champion” for this endeavor, and does he or she meet the attributes outlined in the article? Will this individual have the time, desire, patience, and diligence to provide training on each machine for new anesthesiologists, nurse anesthetists, anesthesiologist assistants, anesthesia technicians and technologists, and biomedical equipment technicians? How will those responsible for training receive expensive manufacturer training on so many machines? The learning curve for competency on multiple machines will be far greater than the learning curve for one machine. Training alone sounds like a near full-time job for someone even with a modest turnover of anesthesia providers. For academic institutions, an in-depth approach to training residents cannot be met if the goal is to expose all residents to such a wide range of machines. How does one handle the first 6 months of anesthesia training, when students are facing a different machine each day while trying to learn so many aspects of anesthesia care?

Interchangeability. The multi-model/manufacturer selection is even less compelling given that every manufacturer and model available offers a unique range of solutions for the clinical problems that providers face. Objectively viewed, while there may be significant differences in operation and use, there probably are not sufficient differences in performance or features to have some of each available. Other issues, such as complexity of managing service arrangements, interchangeability of vaporizers and other components, familiarity of technical personnel with simple troubleshooting routines, etc., suggest that there are serious problems with this approach.

Safety. The safety issue is serious, since the “new provider danger period” is significantly

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Hazards of Machine Diversity

“Q&A,” From Preceding Page

extended, and affected not only by time-on-machine, but now by incidence of exposure to EACH machine. Providers who work intermittently (part-time or PRN), are going to be in the position of working with equipment with which they are only marginally familiar. New systems will incorporate more sophisticated modes of ventilation and monitoring, requiring the operator to be proficient on multiple machines that they may work with infrequently. Proficiency must include topics ranging from basic operation and understanding to the design features and troubleshooting. Proliferating anesthesia machines from multiple vendors, and perhaps multiple models from the same vendor, could potentially become a breeding ground for human error, especially in stressful situations. And, if this is a teaching OR, the safety issue is even more serious, since residents and students are trying to learn many diverse aspects of anesthesia care and should not have their attention diverted from patient care to learn the setup, machine checkout, nuances of operation, and troubleshooting of many different machines.

Technical Support. Issues related to the ownership and support of multiple anesthesia machines from numerous vendors would present significant challenges to any hospital. The issues include training of technologists and support staff with documentation of competency, spare machines, spare parts, a variety of disposables, as well as introducing interface complexities to patient monitors and record-keeping systems, and monitoring and maintaining multiple service contracts.

Economics. There are economic reasons to use only one type of machine, such as volume purchase discount, smaller stock of disposables, and lower training costs. For example, oxygen fuel cells and CO₂ absorbent cartridges may not be universally compatible and would need to be

stocked for each of the machine types. Record-keeping would also vary from machine to machine and could cause patient record problems. If a patient problem results, the cost to deal with the problem would most likely be at least the cost differential of buying one brand of machine over another.

Compromise. If there are multiple machines in a large institution, perhaps the best approach would be to populate different surgical sites with different types of machines. For example, the main operating room suite could have a single type of machine; the outpatient surgery center could have another type of machine, and the pediatric hospital yet another type. For the providers who live in each one of these single environments, there would be no issue with using a different machine each day. This might fit best for academic training programs that typically follow monthly rotations. The anesthesia providers at each site would only have to learn a single machine, thereby increasing patient safety and greatly reducing the learning curve for attaining proficiency.

Summary. Multiple models and manufacturers of anesthesia machines represent a number of potential hazards with additional liability, and will ultimately cost the hospital a great deal more money to support. Is it appropriate to make that milieu even more complex to new providers by adding the difficulties of learning how to operate and effectively use multiple potentially very different anesthesia machines?

Additionally, new microprocessor-based anesthesia machines come with the potential for undiscovered catastrophic failure modes. With multiple new machines the likelihood of discovering some of these modes at an inopportune moment in a given suite of operating rooms will increase. Our consensus is that the concept of placing multiple different anesthesia machines in a single suite of operating rooms is seriously flawed.

Machine Obsolescence

Response to Q&A:

In response to the Q&A article on older machines (*APSF Newsletter* 2008;22(4):78), I would like to report that we are replacing our 2 Narkomen 2B machines in 2008 after 24 years of service. The “near” 100% non-failure rate involved only 2 in-flight failures. One was a sticky valve, replaced in flight, and the other an electronic display failure easily remedied with a replacement board.

Our greatest safety issue over these 24 years was certainly not the machine but the primitive agent level gauge on the vaporizers. An exception to this statement is the Ohmeda Tec 6 plus vaporizer, with its light and squawk alarm before the vaporizer is empty.

In evaluating the new machine choices available, it is discouraging to still see vaporizers with a 10¢ glass tube for an agent level gauge.

My question is, in light of unwanted patient movement or patient awareness from an empty vaporizer, why do we continue to utilize such a poor agent level gauge? Is it a patent restriction that allows only the Ohmeda Tec 6 vaporizer to have a safe agent level alarm? Or is it because we clinicians are requesting the machine engineers to provide larger drawers, a writing shelf, or a better cockpit light instead?

I welcome any response.

Robert R. Jirgl, CRNA
Dowagiac, MI

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Manufacturers Can Also Help Reduce the Chance of Coring

by Jonathan V. Roth, MD, and
Matthias L. Riess, MD, PhD

After a needle is inserted through the stopper of a medication vial, a small piece of the stopper is sometimes sheared off (known as coring) and may not be noticed. This small foreign body can then be aspirated into a syringe and injected into a patient. For many years, the contamination of parenteral fluids and medications by particulate matter has been recognized as a potential health hazard and has been associated with adverse reactions ranging from clinically occult pulmonary granulomas detected at autopsy to local tissue infarction, pulmonary infarction, and death.^{1,2} Riess and Strong recently reported a case where a cored piece of stopper blocked the intravenous infusion of propofol during a total intravenous anesthetic (TIVA), requiring the immediate insertion of another intravenous catheter.³ Others have reported coring when drawing up propofol.⁴⁻⁶ The first author has also experienced coring when drawing up vecuronium. Although there are no data, it would seem likely that coring events may be both unrecognized and underreported.

There are strategies that both we and the manufacturers can employ to help reduce or eliminate the risk of coring. If the needle must pierce a stopper, there is a needle insertion technique that reduces the risk of coring during needle insertion through the stopper of a medication vial.⁶⁻⁷ The needle should be inserted at a 45-60° angle to the plane of the stopper with the opening of the needle tip facing up (i.e., away from the stopper). A small amount of pressure is applied and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper. Second, if the stoppers were made of a material that always floated and were of a noticeable color, they would be easier to spot and would be less likely to be injected in a vertically-oriented syringe. In Riess and Strong's report, their coring sank to the bottom of the propofol vial, thus explaining why it was not noticed until it blocked the intravenous catheter.³ Also, medications can be drawn up via a needle with a filter such as that found in various spinal anesthetic kits. It is unclear whether the incidence of coring varies with the use of a blunt fill needle versus a conventional sharp needle.^{3,8}

Another strategy would be to eliminate the need to pierce a stopper with a needle altogether. This can be accomplished in several ways. First, a vial can have a stopper held in place by a crimp ring that is designed to easily peel off (e.g., 2% lidocaine HCl, Abraxis Pharmaceutical Products, Schaumburg, IL). Alternatively, we can remove a crimped stopper with a pliers-like device (e.g., Kebby Decapper, Kebby

Industries, Inc., Rockford, IL). Additionally, the pharmaceutical manufacturers can provide us with single use medication vials where one just pulls off the entire top (e.g., various local anesthetics from AstraZeneca LP, Wilmington, DE), or where syringes attach directly to the vials (e.g., various local anesthetics from AstraZeneca LP, Wilmington, DE). Lastly, medications can be supplied in prefilled syringes (e.g., propofol from AstraZeneca LP, Wilmington, DE). An additional benefit of not having to pierce a stopper is that it removes any concern of latex contamination in latex allergic patients.

We hope this communication will bring to the attention of the readership a probably infrequent but potentially serious problem that is not well known in the anesthesia community. We hope this letter prompts the manufacturers to consider an engineering solution, of which several suggestions were presented above. In the meantime, we should utilize the technique described above when piercing a stopper with a needle, which adds no financial cost and takes at most an additional 1 or 2 seconds.

Dr. Roth is an Associate Professor of Anesthesiology at Thomas Jefferson School of Medicine, Philadelphia, PA. Dr. Riess is with the Department of Anesthesiology, Medical College of Wisconsin, Milwaukee, Wisconsin.

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Letter to the Editor

Lipid Emulsion: The Time Has Come for a Consensus on Treating Systemic Local Anesthetic Toxicity

To the Editor:

We were glad to see positive mention of lipid emulsion therapy for local anesthetic toxicity in the letter by Dr. Baumgarten and again by Dr. Morell in a recent commentary in the *APSF Newsletter*. Dr. Baumgarten's note detailed several suggestions for improving safety of peripheral nerve and plexus blocks and referred to a patient who survived severe, systemic bupivacaine toxicity by virtue of a heroic resuscitation—possible only because there happened to be a primed bypass machine nearby.¹ Unfortunately, despite precautions taken to prevent it, local anesthetic toxicity continues to occur and all patients are not as lucky, nor all outcomes as favorable. The commentary by Dr. Morell reminds readers that lipid emulsion infusion provides a simple, less invasive method of treating systemic local anesthetic toxicity.²

There are now several published case reports of successful resuscitation with lipid emulsion from cardiac arrest from local anesthetic toxicity³⁻⁶ and one related to bupropion overdose.⁷ Symptoms of toxicity were rapidly reversed in all patients, often after failure of standard resuscitative measures including countershocks and adrenergic therapy. Notably, all recovered without cardiac or neurological deficits. Similar cases have also been posted on the educa-

tional website www.lipidrescue.org where clinicians are encouraged to post their experiences and several more are in press (personal communication). We believe the scientific evidence and clinical experience supporting lipid therapy are now sufficient to justify stocking lipid emulsion at all sites where large doses of local anesthetics are used.

Paradoxically, a recent survey by Corcoran et al.⁸ found a general lack of coordinated preparation for these potentially fatal occurrences in US academic anesthesiology departments. The need for a consensus in this area was recognized by the Association of Anaesthetists of Great Britain and Ireland, which recently issued guidelines for treating severe local anesthetic toxicity, (<http://www.aagbi.org/publications/guidelines/docs/latotoxicity07.pdf>). This excellent document goes some distance to remedying the deficiency, but only part way. A universally accepted protocol for treating systemic local anesthetic toxicity would reduce treatment variance, improve physician preparedness and patient safety, and ultimately contribute to the APSF mission: "To ensure that no patient is harmed by anesthesia."

Guy Weinberg, MD
David Mayer, MD
Chicago, IL

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Test Dose is Standard Practice

To the Editor:

In Dr. Ann Lofsky's review of maternal arrest cases for The Doctors Company (Summer 2007 *APSF Newsletter*), she reported on 8 cases in which patients in labor suffered respiratory arrest following epidural anesthesia. For these cases, there was no mention as to whether a test dose was used before the full anesthetic dose was administered. All the other points noted had to do with the management of a total spinal block due, apparently, to inadvertent injection of the agent into the subarachnoid space.

The use of a test dose, to determine whether the needle or catheter is in the epidural or the subarachnoid, has been standard practice for more than 40 years. Whether that simple test was used and recorded is essential to support the statement in the summary: "the above cases are a testament to the fact that it still can and does occur—even when currently acceptable anesthesia practices are followed."

This review treats respiratory arrest after epidural anesthesia as if it were bad luck, or the act of an evil spirit. That may be true from a lawyer's point of view, but it is only a catastrophe (worst case scenario) when the "anesthesia provider" is not trained and equipped to deal with this complication by 1) being aware of its possibility, 2) having the necessary equipment at hand, and 3) having the training and skill to keep the patient ventilated and the circulation maintained. Dealing with an unexpectedly apneic patient is the trained anesthetist's basic skill, but at least the basic equipment of an operating room needs to be at hand. (Note the one good outcome in which the anesthesiologist acted appropriately.) Epidural anesthesia under any other circumstances should not be attempted. It is rarely essential to the safe conduct of a delivery.

Van S. Lawrence, MD
Minneapolis, MN

Letters to the Editor

There Is No Substitute for Reading the Label

To the Editor:

Once again, I find the material in the *APSF Newsletter* to be informative and noteworthy. Once again, I note in the Winter 2007-08 issue (Vol. 22, No. 4) two examples of similar color cues causing confusion between 2 very different drugs. Page 79 discussed why a "blue-blocker" eye shield changed the color of fentanyl labels from the expected blue color to grey, the color of bupivacaine labels. Then, 2 pages later, pictures of similar blue and white packaging that caused a near mix-up of 2 rather dissimilar drugs.

I have always thought that these color and shape clues lead to mistakes when 2 or more drugs are dressed in closely similar clothing. So, why not make ALL labels and ALL drug packaging look as much alike as possible. Look alike—except for a singular difference—the letters printed on the label; letters spelling out the name of the drug, as free as possible from color or shape clues. That way, the health care professional (no providers here, please) could and would only learn the name of the drug by actually reading the label. There would be, to the extent possible, no color or shape differences in the packaging.

Again, the APSF Foundation and *Newsletter* are wonderful tools for improving the safety of patients receiving the services of anesthesia professionals. I am very appreciative of your mission and wish you well. Thank you.

Nicholas Workhoven, MD
Coos Bay, OR

Reader Calls Attention to Change From Baseline Pressure

To the Editor:

Since I have spent a significant part of my academic career investigating the fidelity and accurate recording of invasive blood pressure measurements, I was quite intrigued by the discussion of adverse neurologic outcomes after shoulder arthroscopy in the beach chair position, and how these adverse outcomes may relate to the measurement of blood pressure.¹⁻⁴ In my opinion Dr. Munis hones in on the relevant issues.⁴ Transmural pressure at the level of the head is absolutely NOT the issue; perfusion pressure is! As such, memorizing correction factors for blood pressure at the level of the head (while the patient is in the beach chair position), while taking readings at the level of the heart is a waste of time and effort. Not only is it a waste of time, it diverts one's focus from the real issue. As Dr. Munis points out, the real issue for anesthesiologists is to what degree blood pressure can be lowered from preoperative levels. What exactly is a safe blood pressure? The problem is—we don't know. And it is probably true that decrements in blood pressures that are safe in some patients may not be safe in others. Dr. Munis should be commended for directing our attention to the real issue in these tragic cases; and pointing out why we should not be distracted by the nonissues of transmural pressures, altering transducer height, and "correction" formulas.

Bruce Kleinman MD
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Labetalol Affects Hemodynamics

To the Editor:

I read with great interest the Letter to the Editor "Labetalol May Decrease Cerebral Perfusion in Beach Chair Position," and wish to thank Dr. Lofsky for pointing out important issues related to the clinical pharmacology of labetalol. I would like to mention some additional supporting and relatively underappreciated aspects of this drug and would like to stress the need for us to understand each patient's hemodynamic situation and how our actions affect it.

At our institution we frequently monitor cardiac output and its components with the esophageal Doppler. Monitoring esophageal Doppler hemodynamics confirms and underscores the fact that labetalol's stronger beta-1 blocking decreases heart rate and contractility preferentially. We have seen profound effects on contractility with this drug, including frequent decreases in aortic peak velocities by 50% and greater. Cerebral, as well as overall perfusion, is not well supported with low perfusion pressure, low cardiac output, and low flow velocities.

Anesthesiologists need to be very certain that any method used for decreasing, or increasing, blood pressure is the desired mechanism for the given clinical situation. The mechanism of labetalol-reduced blood pressure is just one example of how little we know about each individual's hemodynamics when we lack objective information regarding left ventricular filling and emptying characteristics, when we lack real-time data as to how our treatments affect these, and blindly give convenient drugs to change the blood pressure one way or another. We need to assure that our therapeutic actions are providing conditions for safe and favorable outcomes, and to do so we need to understand the hemodynamic situation in real time.

Paul W. Corey, MD
San Diego, California



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If My Spine Surgery Went Fine, Why Can't I See?



Ischemic Optic Neuropathy (late exam with optic nerve pallor) (Photo courtesy of Dr. Sohan S. Hayreh, University of Iowa)

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