



The APSF wishes to extend its concern, sympathy, and support for the victims of Hurricane Katrina. This disaster continues to affect citizens of Gulf Coast communities in a devastating way. In addition, health care providers throughout the country have been impacted by this national tragedy.

One relatively small effect of this disaster is the ongoing relocation of the 2005 ASA Annual Meeting, originally scheduled for New Orleans and now moved to Atlanta. Due to several uncertainties, the usual preview of ASA safety-related events cannot be accurately provided in this issue of the APSF Newsletter.

Our readership is directed to the ASA website at asahq.org for the most up-to-date information regarding the ASA Annual Meeting which will be held in Atlanta, Georgia, on October 22-26, 2005.

Complications of Cervical Epidural Blocks Attract Insurance Company Attention

The Doctors Company has noted an alarming incidence of major claims relating to cervical epidural steroid blocks. In fact, the number of claims for these blocks consistently exceeds the combined total of claims for steroid blocks performed at all other levels.

By Ann S. Lofsky, MD

Epidural steroid injections are widely used in the United States to treat chronic and acute pain. It is commonly accepted that these procedures have risks, although the general perception is that their incidence is low. Recent discussions in the anesthesia literature regarding complications of epidural steroid injections include an article in the *Anesthesia Patient Safety Foundation (APSF) Newsletter*¹ and a report of the American Society of Anesthesiologists Closed Claims Project.² The closed claim study reported that 114 out of the 276 claims for invasive pain procedures concerned epidural steroid blocks. Both articles, however, included epidurals performed at all levels (cervical, thoracic, lumbar, and caudal) in their discussions and conclusions.

While malpractice data naturally suffer from the handicap of missing denominators, discussions with our selected anesthesiologists indicate that cervical blocks may not be performed at a substantially higher rate than blocks at other levels and, therefore, may have a true higher incidence of significant complications. The narrowing of the epidural space in the cervical area and its increased proximity to the spinal cord are factors that might lead to higher injury rates when the dural space is unintentionally entered.

Several articles in the literature include prospective and retrospective reviews of large numbers of cervical epidural steroid blocks. These have all reported low complication rates with minimal or no permanent morbidity or mortality.³⁻⁶ Articles that

have described serious complications have largely been isolated case reports referring to 1 or 2 instances of cord trauma causing permanent injury.^{7,8}

The Doctors Company recently collected and reviewed 13 anesthesiology claims involving allegations of arachnoiditis, paralysis, anoxic brain damage, or death following cervical epidural steroid injections. These claims were accumulated over a 3-year period and were generated by approximately 2,800 insured anesthesiologists, only 64 of whom self-identified as full-time pain management physicians. Those claims are discussed with the goals of delineating the risks involved with cervical epidural steroid blocks and identifying possible loss prevention strategies that might help to avoid similar patient injuries.

Claim Characteristics

The patients ranged in age from 31 to 81 and included slightly more females than males. The blocks were all performed at either C5-6 or C6-7 and were done in either the sitting or prone positions with the necks flexed. The needles used, when described in the records, were either #22 or #18 gauge epidural needles. Fluoroscopy was used in all but 1 case, with epidurograms obtained in most cases unless the procedures were aborted. Cord trauma with resulting neurologic injury occurred in 7 claims. Respiratory arrests occurred in 3 claims

See "Cervical," Page 47

Inside:

Insights from a Safety Officer	Page 49
Safety Considerations of a New Drug Formulation	Page 50
Donors	Page 53
Letters to the Editor	Pages 54-59

AHP

Anesthesia Healthcare Partners

Supports APSF Research

APSF gratefully acknowledges the support of
Anesthesia Healthcare Partners, Inc. (AHP)
 in funding a 2006 APSF Research Grant
 that will be designated the
APSF/AHP Research Award.

As a "Sustaining Patron" the
 AHP contribution will also facilitate
 administrative support of ongoing
 APSF safety initiatives.

Check out our new
 and improved
 website at
www.apsf.org

- Grant Guidelines
- Search Engine
- Back Issues of Newsletter
- Safety Links
- Sponsor List
- Foundation Information

User-Friendly & Informative!

**The APSF
 continues to accept
 and appreciate
 contributions.**

*Please make checks
 payable to the APSF
 and mail donations to:*

**Anesthesia Patient
 Safety Foundation
 (APSF)**
 520 N. Northwest Highway
 Park Ridge, IL 60068-2573



The Anesthesia Patient Safety Foundation Newsletter is the official publication of the nonprofit Anesthesia Patient Safety Foundation and is published quarterly at Wilmington, Delaware. Annual membership: Individual - \$100.00, Corporate - \$1,000.00. This and any additional contributions to the Foundation are tax deductible. © Copyright, Anesthesia Patient Safety Foundation, 2005.

The opinions expressed in this Newsletter are not necessarily those of the Anesthesia Patient Safety Foundation or its members or board of directors. Validity of opinions presented, drug dosages, accuracy, and completeness of content are not guaranteed by the APSF.

APSF Executive Committee:

Robert K. Stoelting, MD, President; Jeffrey B. Cooper, PhD, Executive Vice President; George A. Schapiro, Executive Vice President; David M. Gaba, MD, Secretary; Casey D. Blitt, MD, Treasurer; Sorin J. Brull, MD; Robert A. Caplan, MD; Nassib G. Chamoun; Robert C. Morell, MD; Michael A. Olympio, MD; Richard C. Prielipp, MD.

Newsletter Editorial Board:

Robert C. Morell, MD, Editor; Sorin J. Brull, MD; Joan Christie, MD; Jan Ehrenwerth, MD; John H. Eichhorn, MD; Regina King; Lorri A. Lee, MD; Rodney C. Lester, PhD, CRNA; Glenn S. Murphy, MD; Denise O'Brien, BSN, RN; Karen Posner, PhD; Keith Ruskin, MD; Wilson Somerville, PhD; Jeffery Vender, MD.

Address all general, membership, and subscription correspondence to:

Administrator, Deanna Walker
 Anesthesia Patient Safety Foundation
 Building One, Suite Two
 8007 South Meridian Street
 Indianapolis, IN 46217-2922

e-mail address: apsfoffice@aol.com

FAX: (317) 888-1482

Address Newsletter editorial comments, questions, letters, and suggestions to:

Robert C. Morell, MD
 Editor, APSF Newsletter

c/o Addie Larimore, Editorial Assistant
 Department of Anesthesiology
 Wake Forest University School of Medicine
 9th Floor CSB
 Medical Center Boulevard
 Winston-Salem, NC 27157-1009

e-mail: apsfeditor@yahoo.com

Pain And Paresthesia Portend Problems

“Cervical,” From Page 45

with either anoxic brain injuries or death. There was 1 claim each for epidural hematoma with cord compression, persistent headaches with neck spasms, and infarction of the spinal cord with quadriplegia.

Spinal Cord Injury

The 7 claims for spinal cord injury resulting from cervical epidural steroid injections all had MRI evidence of trauma to the cord at or near the level of the attempted epidurals. Imaging descriptions included cord edema, abnormal signals consistent with blood, fluid or contrast material within the cord, cord syrinx, or scarring. Most of these patients had pre-procedure MRIs or CT scans, proving that the findings were new.

Medical records showed that the patients complained immediately, or in recovery, of varying degrees of pain, weakness, or numbness in 1 or both arms and hands and, in 2 cases, 1 arm and the ipsilateral leg. Most patients were treated with steroids. None had surgical interventions. The symptoms tended to improve with time, but all patients alleged some permanent residual disability.

Four of the patients received intravenous sedation before the block—usually a combination of midazolam and fentanyl, with propofol added in 2 of the claims. The issue of conscious sedation during epidural steroid blocks remains controversial. While many anesthesiologists use sedation to increase patient comfort and relieve anxiety, it has been suggested by some authors that sedation might leave some patients unable to complain about pain or paresthesias, which are early warning signs of nerve irritation, before more serious damage is done.^{3,8}

One study reported a series of 5,400 epidural steroid blocks (including 669 cervical procedures) performed without intravenous sedation, with the exception of 5 patients who complained of extreme preoperative anxiety. Only 4 complications were seen in the entire study, none of which involved permanent injury. Many patients commented that the procedure was relatively painless. The authors of this study concluded that intravenous sedation is unnecessary and “heavily sedated patients are unable to respond with the expected pain and paresthesias due to spinal cord irritation in the event of errant needle placement.”³

Sudden patient movement during needle placement or injection of dye or medication was reported in 4 of these claims, including 2 of the 3 patients who were not sedated. The remaining unsedated patient complained of severe pain when the needle was first inserted, but it resolved as the injection proceeded to completion. In the claims involving sudden patient movements, it was the conclusion of

some reviewers that the sudden movement had caused the needle to dislocate and perforate the cord. One reviewer commented that the patient should have been sedated to prevent movement. Since cord trauma is reportedly quite painful, however, other reviewers suggested an alternative explanation that the patients might have moved because of the needle injury and not just prior to it.

It should be noted that in 3 of the claims, when the patient moved or complained of severe pain, the injections were still performed, resulting in dye or fluid visible by MRI within the cord. Reviewers suggested that, in retrospect, it would have been preferable to remove the needles entirely and reinsert them or to have aborted the procedures.

Respiratory Arrest

All 3 of the patients who had respiratory arrests received intravenous sedation, 2 with midazolam and fentanyl and 1 with the addition of propofol. Fluoroscopy was used in every one of these procedures. All of the patients were given cervical epidural injections of bupivacaine and steroids. Interestingly, in the study of 669 uneventful cervical epidurals, the authors used lidocaine for anesthetizing the skin, and then injected only steroids into the epidural space. The authors explained: “Anesthetic agent is not injected into the cervical epidural space to avoid the risk of respiratory suppression resulting from high cervical anesthesia.”³ While it is customary for many anesthesiologists to inject local anesthesia in order to provide more immediate pain relief, possibly extra attention should be given to the monitoring of those patients who might be at a higher risk for difficulties in the event of accidental dural puncture.

Two of the cases involved respiratory arrests in the recovery period, when the physicians were no longer in attendance. One of these patients had a post-procedure brain CT scan demonstrating contrast within the ventricles. Nurses recalled that this patient had “moved violently” during the injection. The third case had sedation administered by a second anesthesiologist while the first performed the epidural steroid block. This patient was noted to be cyanotic and in arrest on being turned to the supine position while still in the operating room, **the monitor alarms apparently having been deactivated.**

Epidural Hematoma

The literature seems to suggest that hematomas following cervical epidural steroid blocks are rare. There have been a handful of cases reported, not all of which involved patients on known anticoagulating drugs.¹ In 1 patient the medical record reported no prior medications known to be associated with clotting difficulties. The procedure note reported that it was difficult to locate the epidural space with the needle under fluoroscopy and that this necessitated

“multiple” attempts. During the evening following the block, the patient noted progressive weakness of all 4 extremities, and an MRI demonstrated a large epidural hematoma compressing the cord. Surgical decompression was accomplished with substantial improvement in neurological function.

Headaches

Headaches were reported by many of the patients with spinal cord injuries, as might be expected post-dural puncture. It was not the primary complaint, however, and was overshadowed by the more alarming symptoms of weakness and numbness. In the 1 patient involving a primary complaint of persistent headaches, the procedure report stated that the #18-gauge Tuohy needle was advanced into the epidural space under fluoroscopy using loss of resistance. At the time of the “pop” through the ligamentum flavum, the patient moved unexpectedly, and CSF returned through the needle. The needle was then slowly withdrawn until the flow of CSF stopped and once contrast injection demonstrated epidural spread, triamcinolone was injected through the needle. In recovery, the patient complained of severe headache and over the next several days complained of neck and back pain and stiffness and numbness of the face. An MRI was unchanged over the pre-procedure studies. A neurologist attributed the symptoms to probable arachnoiditis from steroids entering into the subarachnoid space.

Spinal Cord Infarction

The only claim involving a vascular injury to the spinal cord occurred in a patient who had had a prior successful cervical epidural steroid block by the same anesthesiologist. During the second block, the patient complained of pain and “tingling” on needle insertion. The needle was withdrawn 2 mm, and the injection of local anesthetic and steroid was given. The patient immediately complained of ringing in the ears, but, according to the anesthesiologist, the block was already complete. On arrival in recovery, the patient could not move either arms or legs. An MRI showed ischemia and infarction of the spinal cord in the cervical area, and the neurological diagnosis was probable intra-arterial injection with spasm or occlusion of a vertebral artery branch.

Possible Steps to Decrease the Risk of Injury

One striking finding in reviewing these claims is that most of them included patients complaining of severe pain or moving suddenly during needle placement. This is in stark contrast to a literature report that “hundreds of our patients have commented on the relatively painless nature of the procedure.”³ Pain, paresthesias, and “jerking”

See “Cervical,” Next Page

Pain Management Physicians Proffer Advice

"Cervical," From Preceding Page

movements should be considered significant warning signs of potential nerve injury, and consideration should be given to removing and repositioning the needle before proceeding with any injections, including epidurography. The possible risks of continuing with the block after a known wet-tap should also be considered.

Injections should be given slowly enough to allow patients to report symptoms, such as tinnitus or abnormal "tingling," or pain sensations in response to questioning. Aspiration for possible blood or CSF should always be performed before injecting and ideally should be clearly documented in the procedure note.

Fluoroscopy, while advocated as a safety measure by a number of authors,^{3,9} clearly cannot alone prevent neurologic injury and, while quite valuable, should not provide a false sense of security. Cadaver evidence has shown that the ligamentum flavum, the landmark for the loss-of-resistance technique, frequently fails to fuse in the midline over the cervical interspaces, and that midline gaps were observed in more than 50% of specimens.^{9,10} This might lead to increased difficulty in localizing the space using loss of resistance as a guide.^{9,10} The authors of the study with 669 uncomplicated cervical epidurals performed almost all of their blocks at C7-T1, explaining that "the epidural space above this level is diminutive and associated with higher risk of dural puncture."³

The monitoring of patients undergoing cervical epidural blocks is important both during the procedure and in the recovery period, especially when sedation or local anesthetics are used. Some authors suggest routine monitoring for 30 to 45 minutes after completion of the block.³ Vital signs should be recorded in the patient's chart. Resuscitation equipment and drugs should be readily available, as should personnel trained in their use. This would include the ability to manage the airway and initiate ventilation, if necessary.

The informed-consent process for cervical epidural steroid blocks should be given sufficient time and attention. Procedures performed for chronic pain are, by definition, elective, and patients must understand and accept the risks involved before proceeding. While not all of the risks need to be enumerated, the remote possibilities of neurologic injury or death should at least be mentioned as rare but possible occurrences. That discussion should be documented in the patient's medical record.

Documentation of the procedure itself is also important. Important information includes the patient's position, the interspace selected, the needle size, use of fluoroscopy, the drugs and dosages

administered, and the presence or absence of patient complaints or movement.

The use of intravenous sedation in these cases remains controversial. The standard of care remains broad, leaving it up to an anesthesiologist's own judgment and discretion. Physicians should at least be aware of the issues involved and consider them in making decisions regarding the appropriate dosages and desired levels of consciousness for any given patient.

Practicing pain management physicians offered their own advice for avoiding patient injury when performing cervical epidural injections as follows:

- Try to use the C7-T1 space whenever possible. Epidurally injected substances spread up to 4 interspaces above the site of injection, so most of the cervical discs may be reached from this level while lessening the risk of cord damage.
- Use fluoroscopy to ensure accurate identification of the spinal level.
- Using the prone position may help to avoid unnecessary patient movement, decreasing the risk of dural puncture.
- Avoid particulate steroid injections through the transforaminal approach.
- Limit sedation when possible.
- Encourage patients to communicate unusual symptoms during the procedure, and question them if they appear uncomfortable
- Avoid injecting the drug or contrast material if neuropathic pain is encountered during needle placement.

As baby boomers age, the incidence of back pain is increasing, and the demand for cervical epidural steroid injections will likely continue to increase.¹¹ As with any invasive procedure, the risks must be weighed against the potential benefits to patients in deciding its appropriateness. We are hopeful that open discussion of clinical experiences, including reviews of medical malpractice claims, will serve to make this a more informed decision for both physicians and their patients.

Ann S. Lofsky, MD, is a practicing anesthesiologist in Santa Monica, CA. Dr. Lofsky is a member of The Doctors Company Board of Governors and is a diplomate of the American Board of Anesthesiology and the American Board of Internal Medicine.

References

1. Abram SE. The safe use of epidural steroid injections. *APSF Newsletter* 2004;19:15-16.
2. Fitzgibbon DR, Posner KL, Domino KB, et al. Chronic pain management: American Society of Anesthesiologists closed claims project. *Anesthesiology* 2004;100:98-105.

3. Johnson BA, Schellhas KP, Pollei SR. Epidurography and therapeutic epidural injections: technical considerations and experience with 5334 cases. *Am J Neuroradiol* 1999;20:697-705.
4. Waldman SD. Complications of cervical epidural nerve blocks with steroids: a prospective study of 790 blocks. *Reg Anesth* 1989;14:149-51.
5. Cicala RS, Westbrook L, Angel JJ. Side effects and complications of cervical epidural steroid injections. *J Pain Symptom Manage* 1989;4:64-6.
6. Botwin KP, Castellanos R, Rao S, et al. Complications of fluoroscopically guided interlaminar cervical epidural injections. *Arch Phys Med Rehab* 2003;84:627-33.
7. Wilkinson PA, Valentine A, Gibbs JM. Intrinsic spinal cord lesions complicating epidural anaesthesia and analgesia: report of three cases. *J Neurol Neurosurg and Psych* 2002;72: 537-39.
8. Hodges SD, Castleberg RL, Miller T, et al. Cervical epidural steroid injection with intrinsic spinal cord damage. Two case reports. *Spine* 1998;23:2137-42.
9. Stojanovic MP, Vu TN, Caneris O, et al. The role of fluoroscopy in cervical epidural injections: an analysis of contrast dispersal patterns. *Spine* 2002;27:509-14.
10. Lirk P, Kolbitsch C, Putz G, et al. Cervical and high thoracic ligamentum flavum frequently fails to fuse in the midline. *Anesthesiology* 2003;99:1387-90.
11. Johnson DW. Back to the future: epidurography. *Am J Neuroradiol* 1999;20:537.

Reprinted by permission of The Doctors Company. All rights reserved.



Contact Information

Anesthesia Patient Safety Foundation
 Building One, Suite Two
 8007 South Meridian Street
 Indianapolis, IN 46217-2922

President: Robert K. Stoelting, MD
 Administrator: Deanna M. Walker

Please address all inquiries by
 email (apsf@apsf.com) or
 facsimile (317-888-1482).

Insights from a Patient Safety Officer

Kenneth J. Abrams, MD, MBA

The Role

Five years ago the safety officer was a member of the health care team with knowledge, expertise, and experience in fire and environmental safety. Today, that has changed significantly. The role of the Patient Safety Officer (PSO) has emerged as a new frontier for the development of critical work needed to improve the likelihood of a successful health care experience for patients. The Institute of Medicine's (IOM) report, "To Err is Human," brought to light the breadth and depth of harm that was being experienced in American health care and called for action to be taken to address these important patient care issues.¹ As the public is seeking greater accountability, payers are seeking improved performance, and the health care community is seeking ways to regain trust, the role of the PSO is developing into a pivotal component for transformational change.

Patient safety requires high level leadership and systems thinking. As such, the PSO is usually a senior level position within the organization, working with both administrative and clinical leaders. While reporting relationships may differ from organization to organization, it is imperative that the PSO have a strong partnership with the CEO to successfully develop and deploy a comprehensive patient safety program.

Many critical initiatives in the health care domain affect the daily work of a PSO. Two of these are the JCAHO's National Patient Safety Goals and the Institute for Healthcare Improvement's 100K Lives Campaign. While these are goals and initiatives, they are not a recipe for transformation and implementation. The PSO needs to create a program of change around the following key areas:

1. The culture of safety
2. Adverse event analysis
3. National initiatives
 - a. Operational process change
 - b. Health information technology

Although a detailed explanation of these facets of safety is beyond the scope of this article, I will attempt to define key objectives of each element.

A culture of safety can be defined as an integrated pattern of individual and organizational behavior based upon shared beliefs and values, that continuously seeks to minimize patient harm that may result from processes of care delivery.² A strategy to develop a just culture employs 2 complementary ideas. First, it creates a system that encourages reporting of injuries and near misses and keeps individuals safe from blame, shame, and retaliation.³ Next, the value imparted by open reporting promotes the creation of reliable care processes, which goes beyond vigilance.

Adverse event systems have 2 major components: methods of detecting adverse events and methods of analyzing adverse events. Since most current systems of adverse event detection rely on voluntary reporting, the vast majority of adverse events go undetected.⁴ Unfortunately, much of the current assessment of adverse events is retrospective. One hopes, as information technology continues to penetrate the health care delivery system, automated detection of potential events will help eliminate harm. Implementation of automatic detection systems requires the emergence of precise terminology in order to be effective.

One of the most recognized national initiatives aimed at operational process change is the 100K Lives Campaign, launched on December 16, 2004, at the IHI National Forum.⁵ The campaign employs 6 changes in care aimed at preventing avoidable deaths. For additional information, visit www.ihf.org/ihf/programs/campaign/. The IOM has made several recommendations focused on improved information systems to support patient safety as a standard of care in hospitals, doctors' offices, and every other health care setting (IOM, 2004).

Bringing these initiatives to life is the role of the PSO and his or her team. Leading patient safety initiatives takes fortitude and leadership. A PSO will be asked to work on all of the previously mentioned initiatives and integrate them into a comprehensive plan of action. In order to do so, a number of critical skills are required. Fundamentally, a PSO needs to be a change agent, working through a plethora of competing and sometimes conflicting agendas. Transformation, execution, and people skills represent the 3 broad categories of leadership competencies needed to be a successful PSO. The technical and behavioral characteristics that comprise these categories cover the spectrum of leadership skills, including communication, initiative, performance management, innovative and strategic thinking, talent development, and professionalism, to name a few.

The Opportunity

Anesthesiologists and nurse anesthetists are uniquely suited to serve as PSOs. Many already are leading national efforts to enhance patient safety. As anesthesia providers, we possess a broad understanding of the complexities of delivering care in a wide variety of environments. We deal with medical management, technical procedures, the young and old, the sick and well, as well as the critically ill and injured. We understand the value of team approaches in the provision of care. We understand the value of equipment checks before providing care.

We have led the development of patient safety, and have dramatically reduced perioperative mortality through systematic analysis, program development, and widespread deployment. Our leaders

have developed standards, guidelines, and practice parameters to provide anesthesiologists and nurse anesthetists with the fundamental elements needed to deliver safe care. We have raised the bar, by choice. In doing so, we have become the benchmark for safety-first medical care, as evidenced by the recent article in the *Wall Street Journal*.⁶

Now we need to further develop our leadership by cultivating the interdisciplinary relationships and partnerships needed to promote the development of a safety agenda across all specialties. I would ask you to consider the following:

- Could a pre-procedural safety check of all procedural equipment eliminate device-related injuries?
- How can we use our knowledge and understanding of the closed claims project to promote knowledge creation within other specialties?
- What would the impact on patient safety be if we could engage all specialties to adopt our commitment to safe care?

We have been criticized for developing key components of clinical care and then leaving them for others. Notably, anesthesiologists helped to develop critical care units, yet, over time, we have become progressively less involved in critical care medicine. We cannot allow this to happen with patient safety. We must demonstrate the commitment and leadership needed to sustain anesthesiology leadership in safety development. We must create the infrastructure to enable process development, systems technology, cross-fertilization, and interdisciplinary collaboration. In short, we must continue to build upon our strengths, for the benefit of all patients.

Dr. Abrams is Chairman of Anesthesiology and Perioperative Medicine, and Patient Safety Officer at AtlantiCare in Pomona, NJ.

References

1. Kohn, LT, Corrigan, JM, and Donaldson, MS, editors; Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academies Press, 2000.
2. Kizer, KW. Large system changer and a culture of safety. In: *Enhancing Patient Safety and Reducing Errors in Health Care*. Chicago: National Patient Safety Foundation, 1999.
3. O'Leary DS. Perspectives and Insights. Council on Teaching Hospitals, Spring Meeting. Joint Commission on Accreditation of Healthcare Organizations. Phoenix, AZ, 2003.
4. Bates DW, et al. Detecting adverse events using information technology. *J Am Med Inform Assoc*. 10(2):115-128, 2003.
5. Institute for Healthcare Improvement. 100k lives campaign. *IHI National Forum*. Orlando, FL., 2004.
6. Hallinan JT. Once seen as risky, one group of doctors changes its ways. *Wall Street Journal*, June 21, 2005.

DepoDur™: A New Drug Formulation With Unique Safety Considerations

by Eugene R. Viscusi, MD

DepoDur™ has recently been added to our choices for postoperative pain management following major surgery. DepoDur™ is an extended release formulation of morphine in a liposomal carrier, specific for epidural administration (Figure 1). DepoDur™ is approved for the treatment of postoperative pain by single dose administration into the lumbar epidural space before major surgery or following umbilical cord clamping during cesarean section. DepoDur™ is not intended for intravenous, intrathecal, or intramuscular administration. It also has not been evaluated in children or for thoracic epidural administration. DepoDur™ also has some unique safety considerations that impact the timing of DepoDur™ administration after a local anesthetic test dose and restrict the concomitant use of local anesthetics.

Recently published studies have demonstrated the safety and efficacy of DepoDur™ in a variety of surgical models. In a hip arthroplasty study, DepoDur™ provided analgesia for up to 48 hours after surgery with a side effect profile similar to standard epidural opioid analgesia.¹ Patients rated their pain control with DepoDur™ as superior compared with intravenous patient controlled analgesia with fentanyl (Figure 2). Patients who received any dose of DepoDur™ had a marked reduction in their need for supplemental analgesia (Figure 3) and delayed the time for first analgesic rescue. No additional analgesia was needed in 25% of patients. Similarly, in the lower abdominal surgery study, patients who received DepoDur™ needed less supplemental opioid analgesia and had significantly reduced pain scores.² Fewer DepoDur™ patients required supplemental analgesia.

In a study with cesarean sections, DepoDur™ was compared to a standard epidural morphine dose of 5 mg.³ Patients who received DepoDur™ at the 10 and 15 mg dose had both superior pain relief and extended analgesia for 48 hours with less need for supplemental analgesia. In order to measure functionality of patients, a measurement instrument was created to assess the impact of pain on common patient functions (resting in bed, sitting, waking, and using the rest room). Pain had significantly less impact on functional ability for 48 hours after surgery in patients who received DepoDur™ at the 10 or 15 mg dose.

The overall side effect profile from the above studies was consistent with the postoperative populations studied and with side effects of neuraxially administered opioids in general. For example, pruritus, nausea, vomiting, and decreased oxygenation occurred in greater than 10% of patients. Overall, up to 4% of patients received naloxone for respira-

tory depression. At approved doses, all incidents of respiratory depression requiring naloxone administration occurred by 16 hours. There were no surprising adverse events.

The potential of providing extended analgesia without an epidural catheter and epidural pump or IV-PCA pump is very desirable. External pump technology is cumbersome for the patient, time consuming for the nursing staff, and is associated with medication errors and pump programming errors. In many surgical settings, anticoagulation to prevent venous thromboembolism is now standard care. Consequently, indwelling epidural catheters may increase the risk of epidural hematoma formation. DepoDur™ may provide extended analgesia without the need for indwelling epidural catheters and without the difficulties associated with current epidural and IV-PCA pumps.

These studies along with the information contained in the package insert⁴ provide some guidance for clinicians introducing DepoDur™ into their clinical practice. Approved DepoDur™ doses are 10 mg for cesarean section, 15 mg for major lower extremity orthopedic surgery, and 10 to 15 mg for lower abdominal and pelvic surgery. Other than cesarean section, some patients may benefit from 20 mg, but clinicians must remember that the incidence of respiratory side effects is dose dependent. One must bear in mind that these doses are based on studies employing opioids alone for analgesia. In practice, most clinicians utilize multimodal analgesic techniques to reduce opioid requirements and their related side effects while optimizing pain relief. If clinicians use similar techniques with DepoDur™, it is quite likely that lower doses may provide adequate analgesia while reducing typical opioid side effects such as nausea, pruritus, and respiratory depression. Also, clinicians may want to consider starting at lower doses while they gain experience with a new drug therapy.

Clinicians must bear in mind that the chief hazard of opioids including DepoDur™ is respiratory depression. This risk is heightened in the elderly, debilitated, and those with underlying respiratory issues. Opioid dose adjustment may therefore be warranted. Hence, clinicians should maintain a high level of vigilance in these populations. Patients receiving opioids require monitoring. If the analgesic efficacy of DepoDur™ lasts for 48 hours, it is reasonable to assume that monitoring for safety is needed over this period. This requires patients to remain in a hospital setting for at least 48 hours.

Concomitant Use of Local Anesthetics

DepoDur™ is not indicated for use after a conventional local anesthetic epidural. There should be



Eugene R. Viscusi, MD

at least a 15-minute waiting period after a standard 3 ml epidural test dose of lidocaine with epinephrine. In studies of drug interactions with DepoDur™ local anesthetics increased the release of morphine from the carrier. Currently, DepoDur™ cannot be given following a true epidural with local anesthetics since the effect on morphine release is unknown. Investigations of this interaction are underway and an answer may be forthcoming. Similarly, no other drug should be placed in the epidural space within 48 hours of DepoDur™ administration because the effect on the release profile of morphine from the carrier (DepoFoam) is unknown.

Monitoring

Patients receiving parenteral opioids require observation for respiratory depression. The current monitoring practice for epidural and intrathecal analgesia offers some guidance. Most clinicians have experience with these modalities, and most hospitals have established protocols for monitoring these patients. However, there are no universally accepted standards or published guidelines for respiratory monitoring with opioid therapies by any accreditation body or society. In addition, there is no clear consensus in the literature.

A recent survey of 1,047 anesthesiologists revealed a wide range of monitoring practice with epidural analgesia.⁵ Half of the respondents reported monitoring by direct observation, but without pulse oxymetry at intermittent intervals. Of these, 30% reported hourly monitoring, 36% at 2-hour intervals, and 34% at 4-hour intervals. Continuous pulse oxymetry was reported by approximately 30% while regular but intermittent use was reported by 15% (5% responded "other"). Clearly, there is a wide range of opinion as to what is appropriate monitoring for these patients. No defined "standard of care" currently exists. Monitoring protocols for epidural analgesia and possibly other analgesic techniques might benefit from an evidence-based approach.

See "DepoDur™," Next Page

Appropriate Protocols Needed for DepoDur™

“DepoDur™,” From Preceding Page

There is clearly a move toward increased concern in treating postoperative pain. The JCAHO pain management standards provided impetus for hospitals to review their pain management practices. Although patients have clearly had the benefit of increased pain awareness, the more aggressive use of analgesics, particularly opioids, has inherent potential risk. Fortunately, opioid-induced respiratory depression is easily managed, when it is recognized. Consequently, a careful review of current practices and adverse events is warranted.

Future Directions

Extended analgesia without an indwelling epidural catheter or external IV-PCA pump may offer distinct benefits for clinician and patient. Further outcome studies will be needed to quantify the potential for easier patient mobility and less burden of care associated with new technologies. As clinicians introduce new modalities, they must assess the risk-benefit ratio for their particular practice and hospital setting. Crafting appropriate protocols and monitoring practices will improve the safety while offering patients the benefits of newer therapies.

Dr. Viscusi is the Director of the Acute Pain Management Service at the Thomas Jefferson University in Philadelphia, PA.

Disclosure:

Dr. Viscusi has received investigative grant support from and has been compensated as a scientific advisor by Endo Pharmaceuticals, manufacturer of Depodur™. He owns no stock in this company, nor does he receive a salary from Endo Pharmaceuticals.

References

1. Viscusi ER, Martin G, Hartrick CT, et al. Forty-eight hours of postoperative pain relief after total hip arthroplasty with a novel, extended-release epidural morphine formulation. *Anesthesiology* 2005;102:1014-22.
2. Gamgling D, Hughes T, Martin G, et al. A comparison of Depodur™, a novel, single-dose extended-release epidural morphine, with standard epidural morphine for pain relief after lower abdominal surgery. *Anesth Analg* 2005;100:1065-74.
3. Carvalho B, Riley E, Cohen SE, et al. Single-dose, sustained-release epidural morphine in the management of postoperative pain after elective cesarean delivery: results of a multicenter randomized controlled study. *Anesth Analg* 2005;100:1150-8.
4. DepoDur™ full prescribing information, Endo Pharmaceuticals (Chadds Ford, PA) 2005 Package Insert.
5. Viscusi ER, Witkowski TA. Monitoring practice for epidural analgesia. Presented at the ASRA 2005 Annual Spring Meeting, Toronto, Ontario, Canada, April 2005, A69.

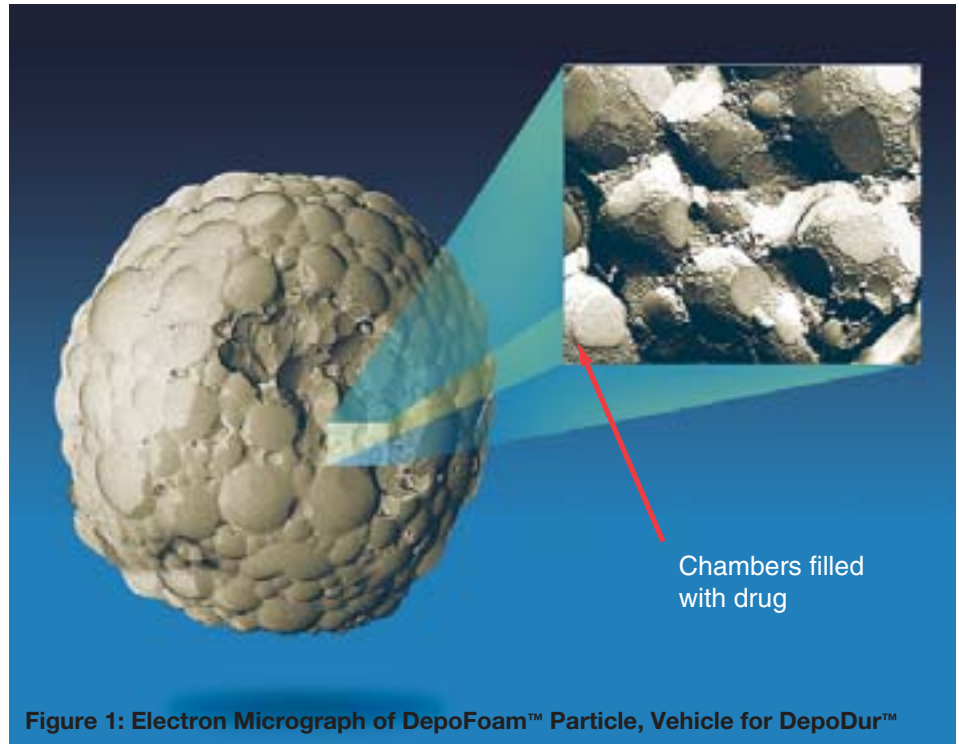
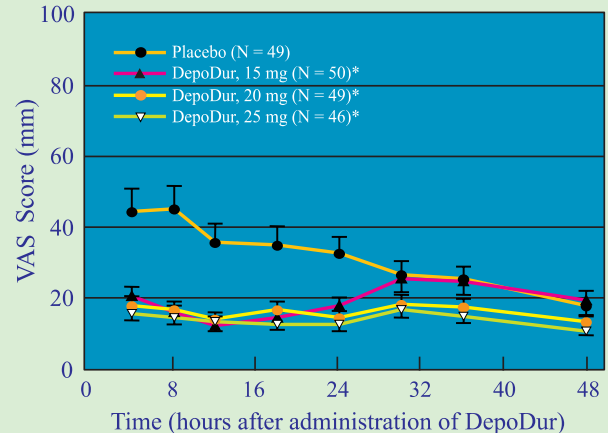


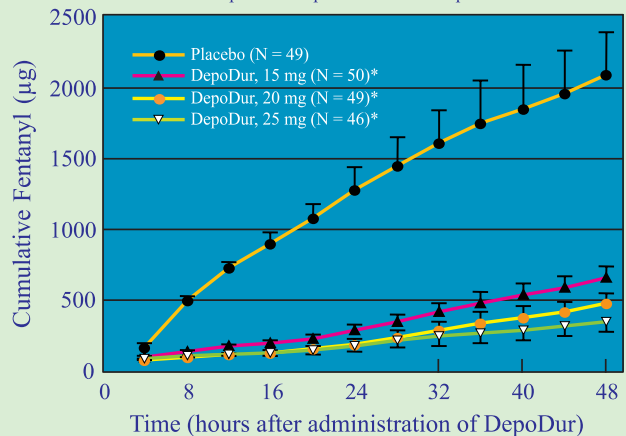
Figure 1: Electron Micrograph of DepoFoam™ Particle, Vehicle for DepoDur™

Figure 2: Pain Intensity Scores Over 48 Hours (Mean, SE)



* P < 0.05 compared with placebo at all time points after 4 hours

Figure 3: Cumulative Fentanyl Usage Over 48 Hours (Mean, SE)



* P < 0.05 compared with placebo at all time points after 4 hours

Dear SIRS

SAFETY
INFORMATION
RESPONSE
SYSTEM



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

Dear SIRS Making a Difference

Dear SIRS:

Recently, I was about 15 minutes into a case with the patient on the ventilator, and several alarms went off, all of the lights on the ventilator lit up, and "vent com error" came up on the screen, followed by the ventilator stopping. Although I am new to using this particular anesthesia system, I remembered reading your article and immediately activated the Ventilator Override button. I continued the rest of the case by manually ventilating the patient. The remainder of the anesthetic was uneventful, with no adverse effects. HOWEVER, had I not read your article, there could have been a misadventure.

Thank you for your efforts.

*James F. Meyer, CRNA
 Sterling, IL*

ERRATUM: Apologies to Mr. Abe Abramovich

Whose title and company were incorrectly printed in the Summer 2005 issue of the APSF Newsletter. The attribute should have been:

**Abe Abramovich, Director, Anesthesia Systems Development
 Datascope Corp., Patient Monitoring Division**

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

SUPPORT YOUR APSF

Your Donation:

- **Funds Research Grants**
- **Supports Your APSF Newsletter**
- **Promotes Important Safety Initiatives**
- **Facilitates Clinician-Manufacturer Interactions**
- **Supports the Website**

Please make checks payable to the APSF and mail donations to:

Anesthesia Patient Safety Foundation (APSF)
 520 N. Northwest Highway
 Park Ridge, IL 60068-2573

Anesthesia Patient Safety Foundation

Corporate Donors

Founding Patron (\$400,000 and higher)
 American Society of Anesthesiologists (asahq.org)

Sustaining Patron (\$100,000 to \$199,999)
 Anesthesia Healthcare Partners, Inc. (AHP)
 (ahphealthcare.com)

Foundation Patron (\$50,000 to \$99,999)
 GE Healthcare
 (gemedical.com)

Benefactor Patron (\$25,000 to \$49,999)

Abbott Laboratories
 (abbott.com)

Aspect Medical Systems
 (aspectms.com)

AstraZeneca Pharmaceuticals LP
 (astrazeneca.com)

Philips Medical Systems
 (medical.philips.com)

Tyco Healthcare (tycohealthcare.com)



Grand Patron (\$15,000 to \$24,999)

Baxter Anesthesia and Critical Care (baxter.com)
 Dräger Medical (nad.com)
 Preferred Physicians Medical Risk Retention Group (ppmrrg.com)

Patron (\$10,000 to \$14,999)

DocuSys (docusys.net)
 Endo Pharmaceuticals (endo.com)
 Spacelabs Medical (spacelabs.com)

Sustaining Member (\$5,000 to \$9,999)

Anesthesiologists Professional Assurance Company
 Arrow International (arrowintl.com)
 Cardinal Health, Alaris Products (alarismed.com)
 Datascope Corporation (datascope.com)
 Kimberly-Clark (kimberly-clark.com)
 LMA of North America (lmana.com)
 ResMed (resmed.com)
 Organon (organon.com)
 Smiths Medical (smiths-medical.com)
 The Doctors Company (thedoctors.com)
 Vance Wall Foundation
 Vital Signs

Sponsoring Member (\$1,000 to \$4,999)

Anesthesia Business Consultants (anesthesiaallc.com)
 Allied Healthcare (alliedhpi.com)

Armstrong Medical (armstrongmedical.net)
 Cerner Corporation (cerner.com)
 Cook Critical Care (cookgroup.com)
 Intersurgical Ltd. (intersurgical.com)
 King Systems Corporation (kingsystems.com)
 Masimo Corporation (masimo.com)
 Medical Education Technologies, Inc. (meti.com)
 Molecular Products Ltd. (molecularproducts.co.uk)
 Oridion (oridion.com)
 Somnia, Inc. (somniainc.com)
 TRIFID Medical Group LLC (trifidmedical.com)
 W.R. Grace (wrgace.com)

Corporate Level Member (\$500 to \$999)

Belmont Instrument Corporation (belmontinstrument.com)
 Boehringer Laboratories (autovac.com)
 Hoana Medical, Inc. (hoana.com)
 Lippincott Williams and Wilkins

Participating Association

American Association of Nurse Anesthetists (aana.com)

Subscribing Society

American Society of Anesthesia Technologists & Technicians (asatt.org)
 American Academy of Anesthesiologist Assistants (anesthetist.org)

Community Donors

(includes Anesthesia Groups, Individuals, Specialty Organizations, and State Societies)

Grand Sponsor (\$5,000 and higher)

American Association of Nurse Anesthetists
 American Medical Foundation
 Asheville Anesthesia Associates
 Florida Society of Anesthesiologists
 Indiana Society of Anesthesiologists
 Robert K. Stoelting, MD

Sustaining Sponsor (\$2,000 to \$4,999)

Alabama State Society of Anesthesiologists
 Anesthesia Associates of Massachusetts
 Anesthesia Consultants Medical Group
 Anesthesia Resources Management
 Arizona Society of Anesthesiologists
 Nassib G. Chamoun
 Georgia Society of Anesthesiologists
 Glenn P. Gravlee, MD
 Iowa Society of Anesthesiologists
 Massachusetts Society of Anesthesiologists
 Michigan Society of Anesthesiologists
 Minnesota Society of Anesthesiologists
 Ohio Society of Anesthesiologists
 Old Pueblo Anesthesia Group
 Pennsylvania Society of Anesthesiologists
 Sanford Schaps, MD
 Society of Cardiovascular Anesthesiologists

Contributing Sponsor (\$750 to \$1,999)

Academy of Anesthesiology
 Affiliated Anesthesiologists, Inc.
 American Society of Critical Care Anesthesiologists
 J. Jeffrey Andrews, MD
 Anesthesia Associates of Northwest Dayton, Inc.
 Anesthesia Services of Birmingham
 Arkansas Society of Anesthesiologists
 Association of Anesthesia Program Directors
 Capital Anesthesiology Association
 Frederick W. Cheney, MD
 Connecticut State Society of Anesthesiologists

Jeffrey B. Cooper, PhD
 David M. Gaba, MD
 John H. Eichhorn, MD
 Illinois Society of Anesthesiologists
 Kentucky Society of Anesthesiologists
 John W. Kinsinger, MD
 Thomas J. Kunkel, MD
 Rodney C. Lester, CRNA
 Edward R. Molina-Lamas, MD
 Madison Anesthesiology Consultants
 Maine Society of Anesthesiologists
 Maryland Society of Anesthesiologists
 Members of the Academy of Anesthesiology
 Michiana Anesthesia Care
 Missouri Society of Anesthesiologists
 Robert C. Morell, MD
 Nebraska Society of Anesthesiologists
 John B. Neeld, MD
 Nevada State Society of Anesthesiologists
 New Mexico Anesthesia Consultants
 Northwest Anesthesia Physicians
 Neshan Ohanian, MD
 Oklahoma Society of Anesthesiologists
 Oregon Anesthesiology Group
 Oregon Society of Anesthesiologists
 Physician Anesthesia Service
 Pittsburgh Anesthesia Associates
 Society of Academic Anesthesia Chairs
 Society for Ambulatory Anesthesia
 Society of Neurosurgical Anesthesia and Critical Care
 Society for Pediatric Anesthesia
 South Carolina Society of Anesthesiologists
 South Dakota Society of Anesthesiologists
 Tennessee Society of Anesthesiologists
 Texas Society of Anesthesiologists
 Drs. Mary Ellen and Mark Warner
 Washington State Society of Anesthesiologists
 West Jersey Anesthesia Associates, PA
 Wisconsin Society of Anesthesiologists

Sponsor (\$100 to \$749)

Anesthesia Associates of Boise
 Anesthesia Associates of Chester County

Anesthesia Associates of St. Cloud
 Robert Barth, MD
 Susan Bender, CRNA
 Paul E. Burke, MD
 Douglas Caceres, MD
 California Society of Anesthesiologists
 Robert A. Caplan, MD
 Cardiovascular Anesthesia, LLC
 CHMC Anesthesia Foundation
 Melvin A. Cohen, MD
 Stuart M. Cohen, MD
 Colorado Society of Anesthesiologists
 Commonwealth Anesthesia Associates
 Paula A. Craig, MD
 Glenn E. DeBoer
 Walter C. Dunwiddie, MD
 Norig Ellison, MD
 Jan Ehrenwerth, MD
 Barry J. Friedberg, MD
 Joseph Gartner, MD
 Georgia Anesthesia Associates
 Barry M. Glazer, MD
 Griffin Anesthesia Associates
 Peter Hendricks, MD
 James S. Hicks, MD
 Dr. and Mrs. Glen E. Holley
 Victor J. Hough, MD
 Howard E. Hudson, Jr., MD
 Idaho Society of Anesthesiologists
 Independence Anesthesia, Inc.
 Indianapolis Society of Anesthesiologists
 Sharon Rose Johnson
 Robert E. Johnstone, MD
 Daniel J. Klemmedson, DDS, MD
 Kansas Society of Anesthesiologists
 Roger W. Litwiller, MD
 Thomas T. McGranahan, MD
 Medical Anesthesiology Consultants Corporation
 Mississippi Society of Anesthesiologists
 Roger A. Moore, MD
 Ervin Moss, MD
 Joseph J. Naples, MD

New Hampshire Society of Anesthesiologists
 New Jersey State Society of Anesthesiologists
 New Mexico Society of Anesthesiologists
 Beverly K. Nichols, CRNA
 L. Charles Novak, MD
 Denise O'Brien, RN
 Jill Oftebro, CRNA
 Michael A. Olympio, MD
 Newton E. Palmer
 Physician's Accounts Receivable
 Mukesh K. Patel, MD
 Gaylon K. Peterson, MD
 Physician Specialists in Anesthesia
 Richard C. Prielp, MD
 Debra D. Pulley, MD
 Rhode Island Society of Anesthesiologists
 Muthia Shanmugham, MD
 Society for Technology in Anesthesia
 Southern Tier Anesthesiologists, PC
 South County Anesthesia Association
 David W. Todd, DMD, MD
 The Woodlands Anesthesia Association
 University of Maryland Anesthesiology Associates
 Utah Society of Anesthesiologists
 Vermont Society of Anesthesiologists
 Virginia Society of Anesthesiologists
 Pamela K. Webb, PhD
 Matthew B. Weinger, MD
 West Virginia Society of Anesthesiologists
 Dr. and Mrs. Wetchler, MD
 Lawrence Wobbrock, JD
 Waterville Anesthesia Associates
 West River Anesthesiology Consultants

In Memoriam

In memory of Gale E. Dryden, MD (friends of the Dryden family)
 In memory of Walter H. Mannheimer (Texas Society of Anesthesiologists)

Letter to the Editor

System Fixes Needed to Prevent Drug Errors

To the Editor:

The following are excerpts from the introduction to the series on patient safety that appeared in the *New England Journal of Medicine*.¹

1. The central message of the recently released Institute of Medicine (IOM) report, "To Err Is Human" was that errors are caused more by faulty systems than individual carelessness.
2. The IOM report made 4 major points: the problem of accidental injury is serious, the cause is not careless people but faulty systems, we need to redesign our systems, and patient safety must become a national priority.
3. The concept that errors result largely from the failures of systems, not from individual carelessness or inadequacy, is fundamental to the new effort to address safety and runs counter to the traditional focus of medical training on individual performance. However, the concept is based on a wealth of studies in cognitive psychology and human-factors engineering, as well as substantial experience in other industries, showing that achieving safety requires more than a reliance on individual carefulness.
4. Changes based on this concept were first introduced into health care in the 1980s by anesthesiologists. Mortality related to anesthesia was dramatically reduced by the use of critical-incident analysis, standardization, and checklists, as well as changes in training and supervision and the nearly universal implementation of new monitoring techniques.
5. Making changes is compounded by the tendency to assign blame for errors, fear of lawsuits, and a focus on individual performance. Not surprisingly, the pressure to improve patient safety has met with some resistance. One concern is that the focus on the system will reduce individual accountability or that the emphasis on safety will divert attention from other aspects of the quality of care.
6. An important barrier to improving patient safety is the confusion and misunderstanding about what the new systems approach entails and how to reconcile it with the need for individual and collective accountability.

These observations were generated as a result of the IOM's report titled "To Err is Human: Building a Safer Health System."² Recently, Leape and Berwick published a follow-up to the IOM report titled "Five Years After To Err Is Human. What Have We Learned?"³ They note that improvements are still possible:

"Five years ago, the Institute of Medicine (IOM) called for a national effort to make health care safe. Although progress since then has been slow, the IOM report truly "changed the conversation" to a focus on changing systems, stimulated a broad array of stakeholders to engage in patient safety, and motivated hospitals to adopt new safe practices. The pace of change is likely to accelerate, particularly in implementation of electronic health records, diffusion of safe practices team training, and full disclosure to patients following injury."

In keeping with the belief that errors result largely from the failures of systems, I would like to point out 3 potentially dangerous anesthesia-related system problems whose easy correction would help prevent adverse outcomes:

1. The first is the similarity in appearance and labeling of drugs (Figure 1). This image shows 4 vials that I recently pulled from a drug tray provided to our anesthesia service by the hospital pharmacy. I was struck by the similarity of the vials as I looked for a vial of ephedrine. The manufacturer apparently attempts to avoid drug swaps by color coding the vial tops (Figure 1, left panel). However, once the caps are removed the vials appear strikingly similar (Figure 1, right panel), making a drug swap extremely easy. A better solution would be to color code the labels and/or change the shape of the vials. For example, potentially dangerous vasoactive drugs could have red labels or be put in square instead of round bottles.
2. The second is the preparation of intravenous fluid bags with air in them. The intravenous fluid bags that are used at my institution contain 50 to 75 ml of air. The problem arises during operations where a lot is happening quickly. When IV bags run dry, a few milliliters of air usually enters the IV tubing, making it necessary to purge the air from the tubing. In an operation where events are changing rapidly (e.g., trauma operations), this is a time-consuming distraction. More important is the problem encountered when IV bags are pressurized to give the fluid rapidly for volume resuscitation. Under these conditions the 50 to 75 ml of air can enter the venous circulation and cause hemodynamic compromise. A worst case scenario would be air entering the CNS or coronary arteries in a patient with an unknown septal defect. Eliminating the air from the bag when spiking it with the IV tubing can minimize air embolism. However, this is time-consuming, and when rapid volume resuscitation is required, purging the air from the bag is inconvenient and often forgotten. This may precisely when venous air embolism is most likely to happen. A better resolution is to

manufacture the bags without air in them. Figure 2 shows a liter bag of IV fluid with air (left) and without air (right). The air-water meniscus does make it easier to determine the volume administered, but even without the meniscus the approximate volume remaining in the bag is not hard to estimate (Figure 2, right panel). Thus, the amount of fluid given is not hard to determine, and the advantage that the meniscus provides in operating room fluid management is minimal.

3. The third system alteration to improve patient safety concerns the daily practice of diluting potentially dangerous vasoactive drugs for the treatment of hypotension. This time-consuming and wasteful ritual occurs daily in all operating rooms. The worst case scenario involves a drug swap where epinephrine is accidentally diluted in the belief that it is ephedrine. Some spinal trays contain epinephrine and ephedrine, making this a distinct possibility. Other swaps of phenylephrine for ephedrine or epinephrine are also possible. A more common error is that which occurs with calculating and making the proper dilution. Also, how much time is wasted daily making these calculations and dilutions? Hospitals no longer ask their staff to dilute KCl because of dilution errors that have caused deaths. It would be an easy system change for drug manufacturers to produce color-coded, 10-ml syringes pre-loaded with ephedrine (5 mg/ml) or phenylephrine (100 mcg/ml). These prepackaged syringes would have a longer shelf-life than those drugs that are manually diluted, and prepackaged syringes would eliminate the enormous waste owing to discarding the manually diluted drugs at the end of each day.

I do not believe that drug swaps will ever be totally prevented, nor am I suggesting that anesthesiologists not be vigilant. It is always good practice to check a vial 3 times: once before opening it, a second time when removing the agent, and a third time before discarding the vial. I do believe, however, that the system changes I propose here will eliminate some of the otherwise inevitable drug swaps.

Donald H. Lambert, PhD, MD
Concord, VT

References

1. Leape L, Epstein AM, Hamel MB. A series on patient safety. *N Engl J Med* 2002; 347:1272-4.
2. Kohn, LT, Corrigan, JM, and Donaldson, MS, editors; Committee on Quality of Health Care in America, Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academies Press, 2000.
3. Leape LL, Berwick DM. Five years after To Err Is Human: what have we learned? *JAMA* 2005;293:2384-90.

See "Errors," Next Page

Look Alike Vials May Contribute to Errors

“Errors,” From Preceding Page



Figure 1: This image shows the similarity between vials of ketorolac, midazolam, and ephedrine. The two leftmost vials of each panel are ketorolac. One of the vials of ketorolac has a black label and the other a lavender label. Both ketorolac vials have a gray cap. Midazolam has a yellow cap and ephedrine has a maroon cap. The colored caps (left panel) help distinguish between the drugs, but once the caps are removed (right panel), the distinctions are less apparent.



Figure 2: The left image shows a liter bag of lactated Ringer's solution as provided from the manufacturer. It contains 50 to 75 ml of air. The image on the right shows the same bag with the air having been removed. The air-water meniscus makes it easier to determine the volume administered. However, without the meniscus the approximate volume remaining in the bag is not hard to estimate (right panel). Therefore, the meniscus provides little advantage in assessing the amount of fluid given in the operating room.

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.

Letter to the Editor

Labor Epidural a Privilege?



To The Editor:

I found it extremely disheartening to read Dr. Parker's comments regarding the "privilege" of receiving a labor epidural. Since when is an epidural a privilege?

If a laboring patient is in need of an epidural, she should not be denied this service because Dr. Parker needs his rest because he has to work the next day, or because she is a Medicaid patient, and it is not financially worth his while to get up out of bed.

Patients who present at night should receive the same quality of safe anesthesia care as patients who present during daylight.

Linda E Ferro, CRNA
Virginia Beach, VA

Editor's Note:

Both Dr. Parker and Ms. Ferro raise important and difficult issues. Labor epidural analgesia has evolved from a procedure prescribed for selected medical indications to the current on-demand, widely available preferred method of labor analgesia. The resources necessary for 24/7 universally available labor epidural analgesia are significant and not always in place. Undeniably, reimbursement and financial support often fall short of covering the cost. Staffing and fatigue must be considered as safety issues as providers struggle with efforts to provide this important service to our laboring obstetric patients.

Letter to the Editor

Anesthesia May Predispose Patients to Corneal Abrasions

To the Editor:

A newsletter dedicated entirely to patient safety is quite a commendable venture and being a regular reader, I wish to utilize this medium to remind the anesthesiology world of corneal abrasion.

Corneal abrasion under anesthesia is rare, but its occurrence results in foreign body sensation in the eye and significant pain and discomfort that can progress to ocular infection and loss of vision if improperly managed.

Any form of anesthesia that leads to unconsciousness can easily predispose patients to this injury. Risk factors may include long duration surgical procedures, lateral positioning, prone position, as well as head and neck surgeries.

The exact mechanisms of the injuries are not clearly understood, but certain preventive measures appear worthwhile to adopt:

- 1) Pulse oximeter sensors should be placed on the ring or fifth finger because most patients, on emergence from anesthesia, are unlikely to rub their eyes with these fingers.
- 2) In general anesthesia, following induction and immediate loss of consciousness and lid reactivity, the eyes should be taped shut preferably from upper lid down, making sure that the eyelids are properly apposed. This may prevent injury during mask ventilation and laryngoscopy from objects on the anesthesiologist's wrist (watches, bracelets), breast pocket (identity cards), and neck (stethoscope, jewelry).



- 3) Use of appropriate sized masks for ventilation as opposed to oversized ones that impinge on the eyes.
 - 4) There is no proven benefit in the use of eye ointments under anesthesia, but a dry cornea is more susceptible to abrasion. In high risk cases, a benefit may be obtained, but care must be taken during application to prevent the tip of the applicator from contacting the eye.
 - 5) Removal of the occlusive tape of the eye at the end of surgery should be gentle and preferably from the upper eyelid to the lower.
- In postoperative clinical situations with a high index of suspicion based on anesthetic events and patient complaints, an ophthalmologic consultation is appropriate.

*Celestine O. Okwuone, MD
Hershey, PA*

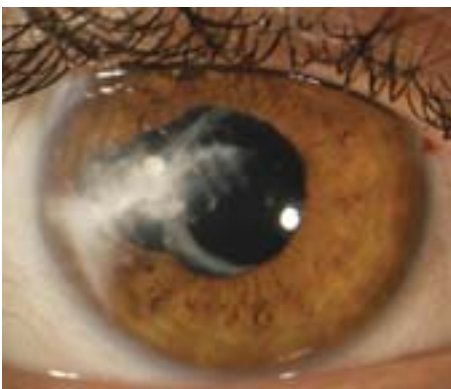


Photo courtesy of Richard Hackel, CRA, Kellogg Eye Center, University of Michigan.

**The APSF wishes to express
their sincere appreciation to
AstraZeneca Pharmaceuticals, LP**

AstraZeneca 

(www.astrazeneca.com)

**for their generous support of
this issue of the APSF Newsletter.**

Letters to the Editor:

MRI Monitoring Done Within Room

To the Editor:

It is interesting that 50% of the participants at a recent renowned anesthesia society refresher course stated that they monitored patients in an MRI scanner from the scanner control room. This same issue was recently covered in the *ASA Newsletter*.

Although I have not given an anesthetic for a MRI in the last 9 years since I retired, I was the principal anesthesiologist doing MRIs at Washington University/Barnes Hospital for 8 years before that, and always monitored the patient from within the scanner itself. The other point is that I usually had the same CRNA working with me, and we both stayed inside the scanner. I am a firm believer in a team approach here.

When we started working with the MRI technicians we were cognizant of their needs, and attempted to help them with a difficult problem when they needed to perform magnetic imaging on a patient who could not remain immobile for the time of the exam. We first started with children and progressed to adults. The MRI technicians were also very helpful to us, and soon allowed us to bring our equipment, although not specialized, into the scanner and showed us where we could safely place the equipment. Recognizing the limitations of the scanner is most important for non-MRI personnel. Having personnel who are accustomed to working inside a scanner is critical.

We learned key lessons about what was compatible with the scanner and what was not. I became the infusion pump when we found out that not every infusion pump works inside the scanner. One of the things to do is to set up a mock MRI scan and try the equipment out and make sure it works first. You should monitor everything inside the scanner just as you do in an OR.

We administered multiple anesthetics for pediatric radiation therapy, which share many of the same considerations, except that you cannot remain inside the generator room while the radiation is being administered, but we were behind the safety screen with a chest stethoscope on the patient's chest plus all the other monitoring for the brief radiation time. If things are not going well with an individual case, do not be afraid to quit and come back another day. We even anesthetized a 34-year-old adult silverback gorilla for an MRI in a regular scanner the same way.

Personnel should not be concerned about the magnetic radiation affecting them as long as they take their credit cards out of their pocket. It has not affected my 21-year-old total hip replacements either. The ASA cannot and should not relax its standard of having anesthesia personnel present in the room during the administration of anesthesia.

Bernard C. DeLeo, MD
Sun City Center, FL

Radiation Therapy Removes Anesthesia Provider from the Treatment Room

To the Editor:

I am writing to comment on a letter which appeared in the Summer 2005 issue of the *APSF Newsletter* titled "Stand Nearby in the MRI" and the ASA basic monitoring standard pertaining to the continuous presence "in the room" of qualified anesthesia personnel throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care. I agree with Dr. Kempen that anesthesiologists and nurse anesthetists should remain within the MRI suite, or "magnet room," at the patient's side throughout the conduct of general anesthesia or sedation during the conduct of MRI procedures.

However, as a pediatric anesthesiologist I am aware of at least 2 specific types of anesthetic cases in which it is unsafe and frankly contrary to radiation safety and health department standards to physically remain "in the room" with a patient throughout the entire anesthetic or sedation case: use of radiation therapy using high-energy x-rays to treat various types of tumors and malignancies, and the use of what is known as a "gamma knife" (focused and directed gamma radiation from radioisotopes) to treat different tumors and vascular lesions. In both instances, when anesthesia or deep sedation is required (usually for pediatric patients), the anesthesiologist must "remotely" monitor the patient via an adjoining room, but beyond sealed doors using a combination of electronic physiologic monitors (including all basic and standard ASA monitors) and either a closed circuit video camera that is aimed at the patient and monitors in the treatment room or a specially prepared window.

Having participated in a number of these cases, I am convinced that the spirit of appropriate ASA monitoring standards is being met, and in fact, the anesthesiologist is typically even more vigilant than normal because of the forced separation and distance from the patient. I have discussed the complex regulatory issues and standards with our colleagues in radiation oncology, and it appears clear that an anesthesiologist would be in violation of a variety of standards* to attempt to remain physically with a patient in a radiation therapy or "gamma knife" room, not to men-

and predictable health risks that the anesthesiologist would incur. This is particularly true in the case of radiation therapy using high energy x-rays, as patients who undergo this therapy generally require daily treatment for a period of weeks. I believe it would be completely inappropriate to deny children (and likely a few adults) who require radiation therapy this palliative or curative treatment because of an apparent conflict with the ASA basic monitoring standard on the issue of continuous presence "in the room" throughout the conduct of all anesthetics.

As we look to the future and various technological advances that may be on the horizon, I think it is likely there will be other types of procedures for which the anesthesiologist or other anesthesia care provider will not be able to physically remain "in the room" with the patient throughout the anesthetic. Perhaps it is time that the ASA consider revising the wording of the basic monitoring standard on anesthesia provider presence to acknowledge and allow for alternative monitoring arrangements when physical presence is unsafe and contrary to other regulations and standards.

Timothy W. Martin, MD, MBA
Little Rock, AR

*The Nuclear Regulatory Commission apparently regulates the safe use, handling, and exposure to radioisotopes. The various state health departments regulate exposure to high energy x-rays produced in an accelerator for radiation therapy, and although the standards vary from state to state, the radiation oncologists I spoke with were not aware of any state where a person other than the patient is permitted to remain within the actual treatment room during exposure of the patient to therapeutic x-rays.



Letters to the Editor:

Where Do You Draw the Line?

To the Editor:

After reading Dr. Lee's "Letter to the Editor" in the *APSF Newsletter*, I felt compelled to write one myself. A few years ago I made a presentation at one of our departmental Morbidity & Mortality meetings regarding "Where Do You Draw the Line?" Dr. Lee's letter also addresses this issue. Too many times the focus is not on the patient and his or her welfare, but instead on whether we are on time with the schedule or whether we can set a new record for turnover time between cases. While performing an anesthetic in a timely fashion is important, I do not feel this should be the focus. No one wants to cancel a case because of last minute findings, but many elective cases are still being done without appropriate test results or actually listening to breath sounds. Obviously, we get away with these transgressions, but luck is not always on our side. Trying to proceed with an anesthetic after treating the patient as if they were one of your own family members (there truly is more thoroughness) is the best way to keep our priorities in line. Pressure to produce from the facility and pressure to keep the surgeon happy should not be the guidelines!

Working in a facility that trains anesthesiology residents and CRNA students adds extra pressure to our need for proper priorities. We are setting the example for these future providers. We have the duty to teach them what proper vigilance and practice entails. As anesthesia providers, our main focus needs to be on doing our best to prevent any harm to the patient. This basic premise actually encompasses a lot. It covers everything from thorough room set-up and anesthesia machine check to essential pre-anesthetic assessment and documentation. Also covered is the need for paying attention to the fundamental tasks of proper positioning, organization, and monitoring. This premise includes keeping the patient properly anesthetized, whatever technique is chosen, from local/sedation, regional, general anesthesia (mask, LMA, or ETT) and the many ranges in between. Vigilant patient monitoring throughout every case is essential. This can only be accomplished if our focus is on "doing our best to prevent any harm to the patient."

Also included in this focus would be regularly reviewing new research and keeping ourselves up to date. I wish I could honestly say that all anesthesia providers have the required focus and priority setting, but unfortunately, many have allowed their "line" to slip beyond what is safe and actually acceptable.

Perhaps, my getting up on my soapbox will be seen as too idealistic, but I sincerely hope not. I hope each of us re-evaluates where we draw our own lines and attempts to relocate them to a safer practice.

Margaret D. Franchi, CRNA, MS
Royal Oak, MI

Brain is Target Organ for Anesthesia

To the Editor:

The article "Down But Not Out; Doctors Disagree How to Best Keep Patients from Awakening during Surgery," which recently appeared in the *US News and World Report*, was an excellent translation of technical lingo for the lay reader, but missed the fundamental point about BIS monitoring.¹ The brain is the target organ for anesthesia. The traditional signs of depth of "sleep" (i.e., heart rate, blood pressure, breathing rate, tearing, grimacing, movement, and so forth), upon which I relied for the first 22 years of my career, do NOT measure the target organ.

Anesthesia is sometimes defined as, "the art of the controlled overdose." Knowing that the traditional signs may be inaccurate, anesthesiologists are obliged to routinely over-medicate for fear of under-medicating. A recent study by Monk et al.² associates a BIS value of less than 45 for more than 2 hours anesthesia time with an **increased** 1-year mortality.

While awareness under anesthesia is indeed a significant problem, practicing anesthesia without a BIS monitor may be a lethal problem!

Curiously, I have heard all of the arguments against BIS monitoring that I heard 26 years ago when I introduced the automatic blood pressure device (Dinamap®) to my hospital. The most telling argument then, as it is today, is, "If they have a machine that can take the blood pressure, for what will they need an anesthesiologist?" The Luddites are still with us. Dr. Sinclair was on the mark when he said, "Why not use the technology?" Fear of losing what remains of one's professional status is the obvious answer.

Barry L. Friedberg, MD
Corona del Mar, CA

References

1. Comarow A. Down but not out; doctors disagree how to best keep patients from awakening during surgery. *US News & World Report* 2005;139(5):52.
2. Monk TG, Saini V, Weldon BC, Sigl JC. Anesthetic management and one-year mortality after noncardiac surgery. *Anesth Analg* 2005;100:4-10.

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



**SUPPORT YOUR
APSF**

*Your contribution is
appreciated!*

**Look for the APSF
at the 2005 ASA
Meeting in
Atlanta, Georgia,
October 22-26, 2005!**

- **Copies of Back Newsletters**
- **Exhibit Booth**
- **APSF Representatives**
- **Make a Donation**

Letters to the Editor:

Reader Weighs in on 3 Letters

To the Editor:

Thank you for your very informative Summer 2005 issue. It brought a few points to mind.

1) The letter "PCA Presents Serious Risks" recalled an incident in my hospital. I had delivered a man after abdominal surgery to the PACU with PCA orders. After some time his nurse called me over for help. The patient's nephew, an orthopedic resident in the hospital, was standing over his bed, pushing the PCA button while the patient was sound asleep. The nurse had tried in vain to stop him. I asked what he was doing, and his response was that he knew his uncle was in pain, but was too sleepy to push the button himself! After carefully explaining to the resident that a sleeping patient was his own safety control, I resolved to change my preoperative talk to patients. I had always told them how PCA worked, but since then I have also emphasized to the families that helping their loved one with the button could kill them. If doctors are unaware of the risk, certainly lay people are.

2) I am genuinely surprised that health care professionals are still reusing needles and syringes. During my residency (back in the 1980s), we routinely reused needles and syringes. In fact, we replaced syringes only when the numbers wore off! But with the rise of the AIDS epidemic that practice stopped, almost instantly. Perhaps, because we're in New York and had a huge awareness of the problem, it was easier for us. There is really no excuse for the practice continuing 20 years later. Needles and syringes cannot cost that much!

3) I wholeheartedly support Drs. Lee and Parker who talked about fatigue in practitioners. As a resident I was aware of being extremely tired after call and have never supported the theory that there is now poor care continuity because of the 80-hour work week, and the "if I did it, you can" mentality with respect to working ridiculous hours. Finances really are at the root of these opinions. My response is get more people on the job to help spread the work and decrease the negative impact on everyone (yes, even in small hospitals). All you need is one lost patient due to fatigue to put it all in perspective.

Again thanks for a great issue.

Saundra E. Curry, MD
New York, NY

Vigilance is Central

To the Editor:

It seems incredible to me that this debate over reading in the OR continues. The emergence of anesthesiology as a valid career choice for the better medical student was not based on income, time off, or the chance to catch up on the latest news while in the operating room. Rather, it was the growing image, due to the efforts of many physicians, of the anesthesiologist as a scientist/practitioner able to "stand tall" in the swirling medical mileau of modern medicine.

Vigilance is the centerpiece of the ASA coat of arms. That means constant watching of the patient, the procedure, and the monitors. We must not rely on the beeps and buzzes of our electronic marvels.

Our image in the medical community is fragile and constantly tested. We must not betray the vital function we supply to the trusting patient. All the outcome studies in the world do not justify this ethical lapse.

We can do better!

W. Sterrett Foster, MD
Louisville, KY

Stay Interested in Your Patient's Care

To the Editor:

I would like to respond to the reader who has softened his view on reading in the OR. I am in total agreement that the image we project is important. However, I am more concerned with honoring the oath we gave, to give each of our patients our undivided attention and total commitment to their care.

I have yet to meet anyone who can "multitask" outside of the tasks at hand and not have one or the other suffer. I cannot find a way to justify giving complex cases 100% of our attention, while the ASA 1 or 2 patient with whom you may be "stuck in a dark room for a couple of hours" be given less attention.

I can tell you without doubt the people who routinely read while trying to administer an anesthetic put aside their reading material during a "patient request" case and give their undivided attention to their friend. No other patient deserves any less, as they are someone's friend, father, mother, or child.

If you are unable to keep yourself interested in your patients' care, maybe you should be in another profession, one that does not involve life.

Linda Hobbs
Dalton, GA

Fatigue Has Been a Problem for Many Years—Time for a Change

To the Editor:

Your article, "Fatigue and the Practice of Anesthesiology" is not only timely, but struck a personal note with me.

As an intern at the University of Pittsburgh Health Sciences Center from July 1955 to June 1956, I worked 36 hours on, 12 hours off, for 365 days—no holidays, no vacations, no sick time. This resulted in 126 hours a week, or 540 hours a month. It took some getting used to, but we all survived, and to the best of my knowledge, so did our patients. But the quality of care had to be seriously compromised toward the end of those 36 hour shifts.

Years later, as a full Professor at the University of Virginia Medical Center, I was still, at age 50, pulling 48 hour weekends on a routine basis. On the fourth of July weekend, 1976, that involved 21 back-to-back major emergencies, which allowed me a total of 45 minutes of sleep (in 3 periods of 15 minutes each) on a stretcher, and 1 cold cheeseburger in 34 hours of virtually constant anesthesia administration. I realized my fatigue and faltering competence when an answer to a simple telephone question came out in the wrong sequence of words, and an attempt to go from one room to another resulted in my walking into the door frame. At this period, I called for back up, and went home to bed.

There can be no conceivable legitimate excuse, short of a mass casualty disaster, for ever requiring people to work such hours. One hopes the people who make out such schedules will read, and heed, this article. How I wish the APSF Newsletter had been published back in the 60s and 70s! Well done!

Terring Heironithus III, MD
Professor of Anesthesiology (retired)
University of Virginia Medical Center
West Virginia University HSC



Improved APSF web site:
www.apsf.org

*Look for the APSF
at the 2005 ASA
Meeting in
Atlanta, Georgia,
October 22-26, 2005!*

- *Copies of Back Newsletters*
- *Exhibit Booth*
- *APSF Representatives*
- *Make a Donation*

Inside:

- *Safety of Cervical Epidurals*
- *Safety Considerations for DepoDur™
A Novel Drug Formulation*
- *Perspective From a Safety Officer*
- *Many Interesting Letters From Our Readers*



The APSF wishes to extend its concern, sympathy, and support for those affected by the devastation wrought by Hurricane Katrina.

Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922

NONPROFIT ORG.
U.S. POSTAGE
PAID
WILMINGTON, DE
PERMIT NO. 1387