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NEWSLETTER

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Special Issue: Dealing with Adverse Events

Despite our efforts, adverse events do occur. Properly dealing with those instances can limit harm, suffering, and conflict as well as prevent future similar occurrences. After an adverse event, support and care must, of course, be rendered to the patient. Less obvious, but of great importance, is communication with the patient and family, including disclosure and attention to the psychological and emotional needs of all involved.

Adverse Events Require Communication and Disclosure

by Sally T. Trombly, RN, MPH, JD

As long as there are humans involved in giving and receiving health care we can expect there will be times when things do not go perfectly. Formalizing the handling of and response to near-misses and actual adverse events has become commonplace in other industries, such as manufacturing and aviation, but only in recent years has the health care sector begun to more broadly apply comparable concepts to the array of services it provides to the public.

New Expectations

In 2001, as part of its accreditation standards, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) instituted a requirement for disclosure of "unanticipated outcomes" targeted at events meeting JCAHO's criteria for designation as a sentinel event. An institutional policy was required, but there was no guidance about addressing disclosure of near misses, admissions of error or fault, or documenting the discussion. No mention of apology appeared in the requirements at all. What resulted were situations where both patients/families and the care providers involved in disclosure discussions would come away feeling something was missing—patients and families saying, "No one ever said they were sorry this happened," and care providers concerned that if they said they were sorry it could be construed as an admission of liability.

As the initial efforts around disclosure have evolved, a more open and balanced way of thinking about disclosure has emerged. This framework recognizes and acknowledges that the disclosure process is not a one-time event. It also places more emphasis on fostering trust and collaboration between patient(s) and caregiver(s) during the ongoing process. There are also now a number of states with statutes that protect expressions of sympathy and compassion from introduction into evidence as an admission of liability in a medical malpractice lawsuit and, in some cases, protect statements of fault made in connection with an apology by a health care provider or institution. Other states have taken legislative and/or regulatory steps to address the issue of disclosure of unanticipated outcomes and adverse events to patients. The *Medical Care Availability and Reduction of Error Act* by Pennsylvania in 2002 requires a hospital, an ambulatory surgical facility, or a birth center to notify a patient (or the patient's family) of a "serious event" in writing within 7 days. The Act defines a serious event as "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient."[1] The medical facility is required to provide written notification within 7 days of the occurrence/discovery of a serious event to the affected patient (or under certain circumstances, to a family member). The Act specifies that the notification does not constitute an acknowledgement or admission of liability.

Communication Factors

Most adverse events are not caused exclusively by a single individual or due solely to the patient's particular disease processes. The situation that arises is more likely to be one in which there has been an adverse event or a poor outcome that involves multiple caregivers and may or may not involve negligence. Patients and families (as well as the caregivers involved) may experience stress not just around the event or outcome itself, but see it increased by subsequent communications and interactions that are not handled well or do not meet their needs at the point in time.

In such complex situations, multiple factors influence the ability of care providers to communicate effectively and for patients and families to assimilate information exchanged during the disclosure process. These can include inappropriate speculation by care providers unable to step back and deal with their own feelings about the event or who may feel compelled to quickly provide an explana-

See "Disclosure," Page 3

Inside:

ASA and AANA Modify Standards to Include Audible Alarms

Due to adverse events occurring in the absence of audible alarms and due to efforts initiated by the Anesthesia Patient Safety Foundation, effective October 25, 2005, the American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring have been modified as follows:

Under Standard 2, Oxygenation, the following has been added:

"When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the anesthesiologist or the anesthesia care team personnel."

Under Standard 2, Ventilation, the following has been added:

"When capnography or capnometry is utilized, the end tidal CO_2 alarm shall be audible to the anesthesiologist or the anesthesia care team personnel."

As with several other standards, under extenuating circumstances, the responsible anesthesiologist may waive these requirements. It is recommended that if this is done a notation should be made in the patient's record, including the reason that this/these requirements were waived.

In a similar fashion, the American Association of Nurse Anesthetists has incorporated new language into Standard V of *The Scope and Standards for Nurse Anesthesia Practice* as follows:

"When any physiological monitoring device is utilized, variable pitch and low threshold alarms should be turned on and audible in most circumstances. The omission of any monitoring standards shall be documented and the reason stated on the patient's anesthesia record."

Please be aware of these changes and keep your alarms on!

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Disclosure and Apology May Not Increase Liability

"Disclosure," From Page 1

tion even though all relevant facts are not yet known. In addition, individual patients and/or family members may not be emotionally ready to listen and fully comprehend, due to feelings of anger or denial over the situation that has arisen. This highlights the importance of recognizing both the readiness and current information needs of the parties participating in the disclosure conversations. In this setting, the existing relationship between the patient/family and the care providers involved faces some of its greatest challenges.

What should go into open and balanced conversations about an adverse event or outcome? Are there ways to meet what may be differing needs of participants on both sides? An obvious first step is to address the patient's immediate clinical needs, the scope of which will vary depending on the situation. The content of an initial conversation related to the event or outcome may be somewhat limited due to the particular clinical circumstances, but should convey the facts needed to make immediate care decisions. The information should be delivered with sensitivity, keeping the patient's and family's best interests in mind, and meeting the patient's need to know.

When a caregiver (or a member of a caregiver's family) is the patient and experiences an adverse event, his/her response is comparable to that of patients who are not clinicians.[2] So one way for caregivers to foster understanding of the value of empathetic disclosure conversations is to envision themselves as the patient (or family member) and think about what questions they would have in that role, and what they'd want to hear. Things that most patients and families want to have included in the conversations include a sincere apology, reassurance that there will be an opportunity for ongoing dialogue, an appropriate investigation of the event or outcome, and the identification/remediation of problems that contributed to the event or outcome focused toward preventing someone else from experiencing the same situation. In addition, the patient would also be awaiting assurance that everything possible is being done to minimize the effects of the mishap. Depending on the situation, conversations may occur over a period of time as additional information becomes available or previous discussions need to be re-reviewed or clarified.

The Impact of Disclosure Conversations

There continue to be questions as to whether disclosure conversations, if done in a timely and open manner, can help to reduce professional liability risk exposure. So far, data on the effects of timely and open disclosure conversations on professional liability risk exposure have been mostly anecdotal or based on research using scenarios and/or mock trials.[3] In addition, a universal difficulty in quantifying the effectiveness of disclosure conversations is related to the variety of professional liability coverage mechanisms present in private practice settings and health care systems in this country and the interaction of those mechanisms with the federal and state legal systems.

Example 1: The Veterans Affairs Medical Center in Lexington, Kentucky. This institution has received favorable publicity for its proactive program of disclosure of adverse events and offers of settlement to patients/families treated within its facilities.[3] What has garnered less notice is the fact that in their system, 1) an individual whose disability becomes increased as a result of an adverse event can have his/her existing compensation level raised, 2) individual federal employees (including physicians) are not named as defendants in lawsuits (the federal government is), and 3) for lawsuits that do arise, the government does not face punitive damages. These factors limit the ability to successfully apply this model in private sector health care systems.

Example 2: COPIC Insurance Company insures more than 80% of the privately insured physicians in Colorado. In 2000, COPIC launched its "3Rs Program," which stands for Recognize, Respond, and Resolve unanticipated medical outcomes.[4] Insured physicians enroll prospectively in the program and agree to accept certain responsibilities. These include the responsibility to initiate the 3R program process by reporting the incident to COPIC and being directly involved in the subsequent processes and interactions. The program offers patients compensation for loss of time ($100/day up to $5,000) and reimbursement for out-of-pocket medical expenses (up to $25,000) paid by the patient. Patients retain the right to pursue legal action, but become ineligible to continue program participation if they submit a written demand for compensation, an attorney or the state Board of Medicine becomes involved, or legal action is instituted. Program data through 2004 indicate payments ranging from $95 to $30,000 occurred in 305 of 930 qualifying incidents.[4] A recent study based on a series of focus groups with participants recruited from COPIC's open and closed 3R cases concluded the collaborative process offered benefits for both patients and providers, and helps reinforce the importance of communication in the relationship between patients and their caregivers.[5]

The Value of Disclosure Conversations

Disclosure and apology, done well, should not increase potential liability. On the other hand, disclosure and apology done in an insensitive manner, based on speculation, or not at all, may ultimately result in deterioration or destruction of trust and the relationship between the patient and caregivers.

According to Dr. Lucian Leape, a noted patient safety researcher, at least 1 trial attorney for plaintiffs has told him "that two-thirds of his clients would go away if doctors and hospitals told them what happened and apologized." This plaintiff's attorney also said he puts the physician in a malpractice case on the witness stand near the end of a trial and asks, "When this happened did you tell the patient you were sorry?" If the answer is, "No, I didn't," the plaintiff's attorney says the jurors get dollar signs in their eyes. "So," he concludes, "It's smart to say 'I'm sorry.' "[6]

Ms. Trombly is the Executive Director of the Dartmouth-Hitchcock Risk Management Program in Lebanon, NH, and is a member of the APSF Board of Directors.

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EDITOR'S NOTE:

Visit www. sorryworks.net which has interesting and useful information from many experts and institutions on the topics of full disclosure and apology.

What to Do After an Adverse Event

By David M. Gaba, MD

After an adverse event, or even after a "near-miss" in which there was no negative outcome, an important consideration beyond the needs of the patient, family, and health care professionals involved is to help to prevent similar events occurring to other patients. Since there are usually systems causes for an event, the same thing may well happen to somebody else—only changes in the way the system does business are likely to have a widespread and lasting beneficial effect. Analyzing events and planning systems changes starts with the individual involved in a particular case, but typically should involve more formal processes as well. Event reporting and analysis systems applicable to the case will vary. Anesthesia departments are required to have internal quality assurance/improvement programs. They also typically have a confidential morbidity and mortality (M&M) conference where difficult cases are discussed. Such peer-review processes are often (but not always) shielded from discovery in litigation, depending on the applicable state and federal laws for the particular patient care setting. Therefore, after any salient event you should complete your department's standard quality assurance report, and if appropriate in your setting, attach a copy of the anesthesia record and any other relevant information.

There is extensive ongoing discussion about establishing national or regional event reporting and analysis systems. In fact the Veterans Health Administration has adapted the voluntary reporting system run by NASA for the FAA for analyzing medical events in VA hospitals (psrs.arc.nasa.gov). The ability to create effective reporting and analysis systems has been greatly increased by the recent passage of federal legislation that provides a strong shield against discovery or use in litigation of the information in the reports or the analyses. Such systems for organizational learning, where they exist, should be used aggressively for the benefit of future patients and future clinicians.

Many institutions have a formal protocol for dealing with serious anesthesia-related events. Dr. Eichhorn's article in this issue discusses the protocol promulgated by the Harvard Hospitals Departments of Anesthesia. A complete description of the protocol by its authors has been published. As we have already described, the first item of this protocol is to attend to the patient. The next step is to contact the department's or division's designated supervising official, who may be the clinical director or the chief of the department. This supervising official becomes the incident supervisor and coordinates the administrative response to the event. For example, the incident supervisor would contact the institution's risk manager and the anesthesia equipment manager (or biomedical engineering service). The Harvard protocol further provides that the clinical director or department chair will designate a follow-up supervisor to coordinate the longer-term activities in response to the event.

When there is any question that equipment, drugs, or other supplies have played a role in an event, it is critical to impound any equipment or supplies that are possibly at fault. It is tragic enough to have a failure contribute to the injury of 1 patient, but sequential injuries to multiple patients have been known to occur. Make sure that the next patient does not also suffer as a result of an unrecognized failure. Even if it is unlikely that equipment failures played any role in the event, the Harvard protocol recommends a routine inspection before it is returned to service. When impounding is appropriate, equipment should either be left in place, or if it must be removed it should be stored in a secure location and labeled "Do Not Disturb," and it should not be altered or manipulated in any way. If there is any suspicion of a drug problem, ampule swap, or syringe swap, all syringes, ampules, vials, sharps containers, and trash should be impounded, as it may be necessary to examine the vials, ampules, or syringes used or even to have assays of their contents conducted.

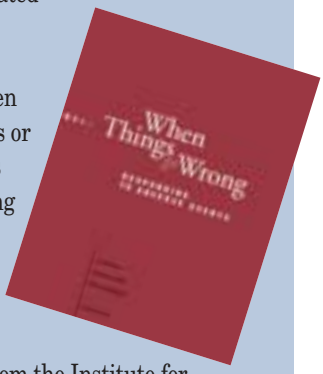
Personnel should resist the impulse to experiment with the equipment to determine whether a fault occurred; they might impede discovery of the real cause. Important information that can be critical to understanding an event and preventing future occurrences may be lost if the state of the equipment is not preserved for detailed analysis. Here is an example: a patient undergoing a major abdominal procedure was anesthetized using significant doses of narcotic, supplemented by volatile anesthetic. On this particular day, the gas analyzer system had capnography operative, but analysis of volatile anesthetics was not. At the time of this event, no brain monitoring technologies were in common use. All went seemingly well during the case, but after regaining full consciousness the patient gave an unequivocal report of intraoperative awareness without pain. The anesthesiologist and anesthesia technician tried to figure out what had happened. They toyed with the vaporizer that had been used, and even removed it from the anesthesia machine to look at. They found nothing, but their attempts made it impossible for biomedical engineers from the hospital or from the manufacturer to make a number of crucial inspections, checks, and tests of the equipment. A leading hypothesis concerning a small misalignment in the placement of the vaporizer on the manifold of the anesthesia machine could not be tested properly, and the cause of the event could not be established. Had the machine been left in the actual condition of the case, it might have been possible to do so.

For events involving medical equipment there may be responsibilities to report the failure to the manufacturer and to the Food and Drug Administration (FDA) under the Safe Medical Devices Reporting Act. Similarly, if problems with or contamination of a drug are found, there may be an obligation to inform the FDA. The risk manager, biomedical engineering service, and pharmacists of your institution should be able to help you to determine whether and how to make such reports.

Dr. Gaba is Associate Dean for Immersive & Simulation-based Learning and Professor of Anesthesia Information Resources and Technology (IRT) at Stanford University School of Medicine. He is also the Director of the Patient Safety Center of Inquiry at VA Palo Alto Health Care System.

When Things Go Wrong: Responding to Adverse Events

is the latest consensus paper of the Harvard-affiliated hospitals that proposes a disclosure when adverse events or medical errors occur, including an apology to the patient. The full paper may be downloaded from the Institute for Healthcare Improvement at



http://www.ihi.org/NR/rdonlyres/A4CE6C77-F65C-4F34-B323-20AA4E41DC79/0/RespondingAdverseEvents.pdf
(See ihi.org for a clickable link.)

Adverse Events May Have Two Victims

by Arnold J. Berry, MD, MPH

"By Apollo the physician . . . I will keep this Oath. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."

The Hippocratic Oath

During medical training, physicians learn the cardinal rule that they are to do no harm to patients. Errors cannot be tolerated. The culture within medical education demands that physicians set high standards for themselves and strive for perfection. Physicians complete their residency armed with the most current and the best training, and many believe that they will be immune from making clinical mistakes in their practice.

In concert with this assumption are patients' expectations that everything will always go well and that, with the advances and discoveries they've heard about so often in the news, bad medical outcomes will not occur. Many patients have developed the perception that complications and errors in the medical system are so rare that they are unlikely to happen to them. But, in spite of our best efforts, at some point in every physician's career, a patient will suffer an adverse outcome. Although much of the practice of anesthesiology has become evidence-based with great improvements in patient safety, daily practice still requires technical skills and judgment, and at times, decisions are made based on imperfect or missing information. A portion of the practice of anesthesiology remains an art, and it is not unexpected that errors, complications, or unexpected outcomes, although unintended, will occur, and the patient may suffer.

When this happens, the anesthesiologist or nurse anesthetist may become a second victim.[1] He or she must cope with the knowledge of having inadvertently brought harm to a patient. Several reactions are common. There may be feelings of guilt, loss of self-esteem, and depression. Professional abilities may be questioned, and there may be the realistic fear of litigation. Doctors have been taught how to counsel patients when an adverse outcome takes place, but unfortunately, they have not learned what to do for themselves under these circumstances.

Then, there is the unavoidable situation of discussing the adverse outcome with the patient or the patient's family. What should be said? How will the injured patient or family react? Physicians may be afraid to admit that an error was made for fear that the information could potentially be used against them during future litigation. This creates an internal conflict forcing the anesthesia provider(s) to hold in any feelings of remorse or empathy for the patient or his or her family. Any open display of emotions will likely be stifled.

Likewise, it is difficult to talk to colleagues about the situation because of the fear that they will question the anesthesia provider's competency or ability to practice. The case will certainly be discussed at a departmental performance improvement conference to identify what went wrong and to make changes to prevent it from happening in the future. But usually this process takes place in a sterile, professional atmosphere without attention to the emotional needs of the affected physician.

Not knowing where to turn and not having a readily apparent venue to openly share feelings, the provider may turn inward looking for solutions. At times, the provider's mechanism for dealing with these complex and strong emotions may be dysfunctional and contribute to depression, substance abuse, or even suicide.[2]

Recent work has revealed that depression and psychiatric disorders are present more commonly than realized among physicians. Surveys of medical students indicate that one-fourth may already suffer from depression.[3] Depression may continue into residency and contribute to burnout during training.[4] Physicians may fail to recognize when they are depressed, or if they do, be resistant to referral for treatment. There are many possible causes for this including concern that action would be taken by state medical boards, insurance companies, or hospital administrators. Additionally, apprehension arises regarding the stigma of a diagnosis of depression and the need for treatment.

Data from centers treating anesthesiologists with addiction indicate that the coexistence of mental disorders is not uncommon.[5,6] Although an association exists between addiction and mental disorders like depression, the attributable risk for substance abuse due to psychiatric conditions has not been determined.

Decades of research have documented that physicians' risk of suicide is greater than for the general population.[7] In 1968, Bruce published data indicating that the rate of suicide in anesthesiologists was 2.7-times greater than for a sample of male insurance policy holders.[8] A more recent mortality study compared causes of death in anesthesiologists to a cohort of internists.[9] The rate of suicide in anesthesiologists was 1.45-times that for the internists, while the rates for drug-related suicide and all drug-related deaths were 2.2- and 2.8-times greater, respectively. A significant proportion of physicians who attempt suicide have coexisting psychiatric disorders, substance abuse, or alcoholism.[7]

Undoubtedly, there are multiple factors responsible for the increased rate of suicide in anesthesiologists and for the cases of depression and addiction. Multiple stresses are present in the professional life of anesthesiologists and nurse anesthetists including the events associated with an adverse patient outcome. Future studies should be directed at determining the extent to which a clinician's reaction to the stress of an adverse patient outcome contributes to depression, substance abuse, and suicide. A better understanding of these relationships will permit more effective prevention and treatment.

But what can be done to help the second victim, the anesthesia provider, when a medical error or an adverse outcome occurs?[1,10] Creation of an open, understanding environment for colleagues to discuss mistakes will reduce the anxiety and shame felt by the individual. Senior staff should be supportive of the affected physician and should encourage dialogue regarding the events that took place as well as the resulting emotions. Departmental and institutional policies and procedures, which are not punitive to the individual, should be in place to facilitate formal psychological counseling when indicated.

The error or the circumstances surrounding the adverse event should be discussed with the patient or the patient's family including an explanation of what happened and an assurance that changes have been made to prevent the event from happening in the future. On an emotional level, an apology or an expression of empathy from the anesthesiologist and/or nurse anesthetist may help assuage the patient's anger to an extent that litigation would not be contemplated. The act may also facilitate resolving the provider's emotions and feelings of guilt regarding the error or adverse outcome. Several states have passed legislation that prohibits apologetic expressions of sympathy from being admitted as evidence of an admission of liability in a civil action. In our legal system that emphasizes adversarial relationships, physicians may be counseled against any statements of apology by their institution's risk management department or legal staff. Until there is universal legislation or widespread court rulings that permit expression of empathy or a formal apology, caution should be taken to weigh the possible value versus the risk of making an apology.

See "Two Victims," Next Page

Policies and Procedures Needed to Support Our Colleagues

"Two Victims," From Preceding Page

To implement these strategies there must be institutional policies outlining what can be discussed among colleagues and how and what information should be transmitted to the injured patient or family. There should be educational programs to inform physicians of these policies and the availability of legal counsel when patient issues arise. More importantly, we must be sensitive to the emotional needs of our colleague, the second victim, when a patient suffers from an error or adverse outcome.

Dr. Berry is a Professor of Anesthesiology at Emory University School of Medicine, Atlanta, GA.

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www.anest.ufl.edu/vam

APSF Grant Application Deadline June 19, 2006

See Winter 2005-2006 Issue or website: www.apsf.org for Application Guidelines!

Letter to the Editor

Residency Programs Need To Emphasize Dialogue Skills

To the Editor:

For those of us involved in residency education, the article in the Winter 2005-2006 issue of the *APSF Newsletter* entitled "Patient Perspectives Personalize Patient Safety"[1] should serve as a reminder that the foundation for establishing effective communication after catastrophic events begins with instruction in basic physician-patient dialogue. The attainment of competency in interpersonal and communication skills as required by the Accreditation Council for Graduate Medical Education can begin by innovative teaching tools and exercises. For the past 2 years, we have used letters from patients who express disappointment in care or formal complaints regarding their perioperative experience as a springboard for discussing effective ways to respond in an organized, empathetic manner.

Instruction in letter composition incorporates the acronym AREA (acknowledgment, regret, explanation, assurance). Our residents are taught that the patient's sentiments must be acknowledged. Whether the physician agrees with the patient's perception of his/her experience is irrelevant: the only reality is the patient's perception. Expression of regret can be very comforting for the patient. Disappointment by the treating physician that certain events led to patient dissatisfaction is just as important in validating the patient's feelings as acknowledgment. An explanation of the events that may have led to a complication or dissatisfaction in the care received is pivotal for resolution. Using layman's language will illuminate facts and fill in knowledge gaps that help the patient understand the chain of events that led to a negative experience. And finally, but by no means less important, assurance is provided that systems changes will be implemented that will reduce the likelihood that someone else might experience the same complication or maloccurrence.

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Life After Death: A Resident's Perspective

by Farnaz Milani Gazoni, MD

I pushed the respiratory therapist aside, took a deep breath, and slid the laryngoscope into her mouth. Three minutes earlier an overhead page had called me to my first code, and here, for the first time without an attending watching over my shoulder, I was intubating this young woman who, for reasons as yet unknown to me, had arrested in her hospital bed. To my utter relief and sheer delight, her vocal cords were in clear view and I passed the endotracheal tube with ease. After confirming placement with the CO_2 detector, and listening to both sides of her chest, I secured the tube and wiped the sweat from my brow. For 1 moment, I felt great relief, even pride. *Well done*, I thought to myself, and prepared myself to see her come back to life.

My sense of satisfaction, however, soon turned to terror as I watched her turn blue despite my successful intervention. My heart was racing. I listened, once again, to her right lung and her left, her right lung and her left, her right lung and her left: bilateral and equal. I listened to her stomach: nothing. I checked again for exhaled CO_2: present. I finally resorted to taking another look at her airway: the tube was between the cords. I watched as the internal medicine intern pounded on her chest, and listened as the oncology fellow called for another dose of epinephrine… atropine… now bicarbonate. But not even 360 joules of electricity could help her. She had become a blue shell and finally there was nothing left to do for her. As the fellow called the code, I dropped my head, knelt down to the floor to collect my instruments and walked away in defeat.

Within a few minutes, I returned to my duties of caring for the patients in our PACU; making rounds, checking X-rays, taking reports from fellow residents. Looking back, I realize that I felt obliged, as a PGY-2, to be perfectly capable of resuming "business as usual." Despite my every effort, however, I was overcome with grief, guilt, and anxiety. I could not get the image out of my head of this young woman's last moments and could not help but wonder if there was, perhaps, something I did or did not do that contributed to her death. One of our attendings happened to be walking through the PACU and noticed the tears welling in my eyes that I was desperately trying to conceal. *For God's sake, Farnaz, don't cry in front of the patients and nurses…. Get a grip*, I told myself on his behalf—I was sure he wanted to. But, instead, he guided me to a small corridor that afforded a bit more privacy and offered me a fatherly hug and an understanding ear. He listened as I recounted our resuscitative efforts and explained to him all of the questions and fears that were racing through my mind. He conveyed extraordinary compassion and empathy. I knew he understood what I was feeling and that he cared. Both verbally and non-verbally, he spoke volumes. His healing presence was calming and I was finally able to control my tears. I took a few minutes to wash my face and clear my thoughts, and went back to work.

The Potential of Compassion

Almost a year later, I look back at that experience and marvel at the boundless potential of compassion. Had it not been for the empathic, caring, and wise counsel of my attending at a moment in time when I most needed it, that same Code Blue would have been just one of many stressful and traumatic experiences, fostering self-doubt, cynicism, and burnout. It would have served to make me a little less caring, less feeling, and less fulfilled in my capacity as a physician. Instead, that same experience, as painful as it was, proved to be transformative, in a positive way. I continued to mourn the death of this young woman for quite awhile. Rather than impinging on my ability to care for my patients, as we are often led to believe such sentimentality would, I found my curiosity enhanced, my patience expanded, my energy revitalized. Everything meant more to me and I, in turn, paid more attention to how I greeted my patients, how I touched them, how I positioned them on the operating table, and how I managed them medically. The need to learn, by reading or listening, as much as I could about human physiology, pharmacology, and disease processes suddenly seemed urgent. The very meaning of my work gained new dimension, and the countless sacrifices I make as a resident now seemed to mean more than simply a means to an end. My work began to feel less like a job and more like a calling. Paradoxically, this experience allowed me to reconnect with the humanistic dimension of our work. I attribute much of this to having had the opportunity to debrief with my attending.

In a broader context, this experience also alerted me to the potential negative impact that the death of a patient might exert on a resident. I started talking to fellow anesthesiology residents who were unfortunate enough to have experienced the intraoperative death or serious injury of a patient, asking them about their experiences and the psychological impact the events had on them. As varied as their personalities, specifics of their stories, and the details of the aftermath were, two things were made clear to me: the intraoperative death or serious injury of a patient is an extremely stressful event for a resident, and the opportunity to speak soon after the incident, in one capacity or another, with an attending who acknowledged and cared about the impact of the stress on the resident, was extremely constructive.

The Stress of Anesthesiology Residency: Disasters and Their Aftermath

Anesthesiology is commonly perceived to be a "high stress" subspecialty. Our disproportionate representation among physicians who commit suicide and physicians in drug rehabilitation programs may be a marker of this.[1,2] While only 3-4% of all physicians are anesthesiologists, anesthesiologists comprise between 9-13% of physicians treated in substance abuse programs.[2,3] A survey of 133 United States anesthesiology training program chairs conducted between the period of 1990-1997 revealed an incidence of known drug abuse of 1% among anesthesia faculty and 1.6% among anesthesiology residents.[1] Residents seem to be particularly vulnerable, with several studies finding high rates of alcohol and drug use. Anesthesiologists are also at greater risk for suicide. The risk to anesthesiologists of drug-related death is greatest in the first 5 years after medical school.[2] While the proposed explanations for these alarming and disturbing trends have yet to be elucidated, they do indicate, I believe, not only the high level of stress in our specialty, but also, and perhaps more importantly, our paucity of skills for coping with this stress in a healthy, adaptive manner.

The ability to stay calm and remain highly functional in stressful circumstances is one of the key skill sets needed to practice anesthesia effectively. We, as anesthesiologists, take pride in our critical care skills and our mastery of life-saving techniques and protocols. Further, our ability to remain level-headed and calm when things are going awry is paramount. Where we are lacking, however, is in skills dealing with the aftermath of such "disasters." For, "the focus of training in anesthesia is concerned with the avoidance of disasters, rather than the management of their aftermath."[4] Our lectures, literature, and simulations rarely, if ever, address the need for developing skills needed to cope with the stress of medical catastrophes such as the intraoperative death or injury of our patients.

Several studies indicate that the majority of practicing anesthesiologists will experience the intraoperative death of 1 patient in the course of their careers. I believe that residents, lacking the benefit of clinical experience and the confidence that years of providing safe and successful anesthetics confers, and given the plethora of added anxieties and pressures of residency, are particularly prone to the psychological stress of such events. In a cross-sectional study of 188 doctors working in 2 academic hospitals in the United States who cared for 68 patients who died, junior

See "Resident," Next Page

Residents Deserve Support After Serious Events

"Resident," From Preceding Page

residents reported needing significantly more emotional support than attending physicians after the death of their patients.[5]

The Need for Support

Many American medical societies, including the American Academy of Pediatrics, for example, have put forth statements acknowledging the impact of patient death on physicians, and the importance of addressing the concerns and needs of the physician after the death of a patient.[6] Our colleagues in the UK have acknowledged the potential impact of perioperative death on the anesthesia provider, publishing guidelines for dealing with the aftermath of anesthetic catastrophes. In 2005, The Association of Anaesthetists of Great Britain and Ireland advised against underestimating the psychological impact on staff following the death or serious injury of an operative patient. In the document, they list ways in which "a catastrophe may affect you personally" and provide suggestions for supportive actions to be taken should a colleague experience an intraoperative death.[7]

Given the heterogeneity of circumstances surrounding patient deaths and of anesthesiologists' personalities and needs, not every anesthesiologist or anesthesiology resident will have the same needs after an adverse event. Further, there is a growing body of literature questioning the efficacy of single-session psychological interventions such as Critical Incident stress debriefing.[8] Nobody likes to be force fed, even when what is being forced is meant to help you. At the same time, some form of organizational support should be provided, I believe, to all anesthesiologists, but especially to residents who experience an intraoperative critical incident. Without the opportunity for open and honest discussion, "feelings of incompetence and isolation and psychological distress such as depression or even symptoms of post-traumatic stress disorder such as sleep disturbance, nightmares, irritability, and problems concentrating, which may even lead to an inability to work, are far more likely."[8] Some time out of the OR may or may not be needed. A demonstration of support and understanding from the institution may be very helpful after an adverse event. In some situations, sitting down with the patient or family to discuss what happened (a practice previously discouraged or even forbidden by the liability insurer) might be of great value. But at the very least, the opportunity to discuss what happened in a confidential, safe, supportive, and blame-free environment—whether it be a team debriefing session including all involved OR staff or simply a discussion with a colleague or mentor over a cup of coffee—would be an easy initial strategy for addressing this important issue. We need to reach a point where every junior resident who experiences a poor outcome despite his or her best efforts will get the kind of compassionate support that I received.

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Letter to the Editor:

Prevention of Perioperative Hypothermia Remains Problematic

The battle to prevent perioperative hypothermia is a battle that anesthesiologists and nurse anesthetists lose all too often. It is bad enough that the realities of human physiology and anesthetic pharmacology are working against us. To add insult to injury our own colleagues and co-workers frequently sabotage our efforts at maintaining normothermia by adjusting the OR thermostat down to near arctic levels.

I read with interest an article in the Winter 2006 *APSF Newsletter* written by Dr. John Eichhorn discussing some of the newest technical products that were on display at the recent ASA meeting in Atlanta. While discussing various products intended to help us keep our patients warm, he mentioned that one item getting plenty of notice was a vest that is intended to warm shivering anesthesiologists, nurse anesthetists and circulating nurses. Apparently it was a real hit at the convention.

The facts regarding the consequences of hypothermia in surgical patients are well documented and profound. Unlike some of the more complicated issues facing our specialty, prevention of hypothermia could easily become a reality if we would simply stand up for our patients and demand that OR temperatures be kept at a "reasonable" level. The evidence is clear that if ambient temperatures are in the range of 74° F, the incidence of hypothermia can be significantly reduced.[1]

Many assume that this is just a fantasy, as our surgical comrades would never allow themselves to be subjected to such inhospitable conditions. I disagree. What we must do is completely rethink our temperature management strategies. Contemporary practice involves placing the patient in a frigid room and then employing a series of expensive active warming measures in an effort to preserve normothermia. All too often we fail. What if our ORs were kept warm enough to avoid hypothermia, and in order to keep our surgical friends content we placed them in their own "micro-environment" which would allow them to be as "cool" as they wanted to be?

Think about it, the surgeons and techs occupy <5% of the total air space of a typical OR, and yet we currently cool the entire room in order to accommodate them at great risk to the patient's health and safety. Existing technology allows individuals to wear lightweight, non-obtrusive vests which circulate cold liquid and allow the wearer to be kept in his or her own comfort zone. Surgeons in many parts of the country are already utilizing these products with great satisfaction.

If we are truly the leaders in patient safety that we claim we are, it is time we demand a complete change in the way this issue is addressed. Using "micro-environment" technology will allow us to keep our patients warm and safe and our surgeons happy. It is entirely possible that cost savings will be realized because the need for expensive disposable forced air warming blankets would be significantly reduced.

Maybe I will cancel my order for that electric warming vest.

J. William Kinsinger, MD
Oklahoma City OK

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Patient and Doctor Reconcile for Greater Good

The following is a rare first-person account of an adverse event told by the patient and her anesthesiologist; a story of pain and conflict followed by healing and reconciliation. A narrative of this event was published in the previous issue of the **APSF Newsletter** *and is available online at www.apsf.org.*

by Frederick A. van Pelt, MD, MBA, and Linda Kenney

The Patient:

Linda (LK): On November 18, 1999, I entered the hospital to have an ankle replacement. I was born with congenital club feet, and this was my nineteenth surgery. I was an otherwise healthy 37-year-old woman, married, and a mother of 3, and for me this type of surgery had become routine. I met with Dr. van Pelt, the anesthesiologist, and we agreed to combine a nerve block with a general anesthetic for this procedure. I encouraged my husband to go to work; after all, we had been down this road may times. I don't remember anything else from the day of my surgery.

I awoke a couple of days later with a large incision down my chest, tubes coming from every which way, and not able to fully appreciate what had transpired. It was only after I was transferred out of the ICU that I was told that I had had a reaction to the anesthesia. I worried about my husband and children and used humor to lighten the atmosphere and remove myself from the event. Although the nurses were compassionate and visibly sympathetic, no one spoke about what had happened. My husband did not receive any counseling or emotional support while I was in the hospital, and when I was discharged home, I was only given wound care instructions and was told that I would have a visiting nurse.

About a week after I was discharged home, I received a letter from Dr. van Pelt. My first thought was that he was doing damage control, and I filed the letter away. I had more pressing immediate concerns, like my physical recovery and my family's emotions around the event. I was just happy to be alive, and I found myself being strong for them emotionally while keeping my own feelings on autopilot. It wasn't until several months had passed and my family and friends were moving on with their lives that I started to truly appreciate the emotional impact to myself. I began feeling survivor's guilt; I survived while others are not as fortunate. I realized that I needed support and called the hospital for services, only to have the calls go unreturned.

By April I decided that I was not going to sue Dr. van Pelt. This decision was based on not wanting to be responsible for ruining his career. And, more importantly, I wanted to get my life back to normal and not drag my family through years of litigation. When I saw how deeply this event had impacted my surgeon, who was not even involved, I realized that this event must have had an impact on Dr. van Pelt. I decided to talk to him, and let him know I didn't harbor any bad feelings. I wanted to forgive him so that I could move on with my life, and I did not want to be responsible for another person living with the burden of almost killing someone without any closure.

I had a burning desire to see what types of support services might be available. As I expanded my search I realized, much to my dismay, that very little support existed for those having been through medical trauma. The need to ensure that other patients and families did not feel unsupported after these types of events became somewhat of an obsession. After the 1-year anniversary, I wrote a letter to the hospital administration sharing my concerns about their lack of support; letting them know it was no longer about me, but the patients/families that followed. I did receive responses to my letters, but they only managed to make me angry. Today I am so grateful for those responses, because they only served to fuel my passion. I was a woman on a mission—I just didn't know it yet!

I received a second letter from Dr. van Pelt around the second anniversary of "the event" letting me know he was back in the area, and to see if I was still interested a face-to-face meeting. The letter was a complete surprise. I never expected to hear from him again. I picked up the phone almost immediately. He had been part of one of the most traumatic and transforming events in my life, yet I had no idea what he even looked like.

The Physician:

van Pelt (RvP): On November 18, 1999, I was involved in an adverse medical event that transformed my life. Linda Kenney, an otherwise healthy, 37-year-old woman with congenital club feet, presented for an ankle replacement. After reviewing the medical record and discussing the anesthetic options with the patient, we decided to proceed with a general anesthetic and a popliteal fossa block for postoperative pain relief.

We performed the popliteal fossa block in the preoperative holding area using the standard precautions: full hemodynamic monitors, O_2 face mask, and light sedation. When we had identified the nerves using a nerve stimulator, we incrementally injected a total of 30 ml of 0.5% bupivicaine without difficulty. At the completion of the block, as we were positioning her supine, the patient suddenly became confused and disoriented, and rapidly progressed to having a grand mal seizure. Recognizing that the bupivicaine had gone intravascular, I immediately called for support, and we watched over the next minute as the patient progressed into hemodynamic collapse by ventricular fibrillation. CPR/ACLS algorithms were immediately started without any success in restoring cardiac function. We realized that given the absent response to resuscitation and the pharmacology of bupivicaine that our best chance of saving the patient would have to involve a more aggressive approach. By good fortune, a cardiac operating room with its complement surgical team was completely set up in expectation of another patient. We took the patient emergently into the room and within 35 minutes of the event she had had a sternotomy and was successfully connected to the bypass machine. Within 2 minutes of being on the pump, the patient's cardiac rhythm was restored and after another hour she was successfully weaned off bypass and taken to the cardiac ICU for recovery.

The impact of what had happened did not really sink in until the patient had been successful weaned off bypass. I felt accountable for the event, and with the surgeon went to talk to the patient's husband, whom we found alone in a small conference room within our Family Liaison area. He had not been given any details about what had happened other than that there had been "a complication with the anesthesia," and he was pacing, frantic and panicked, as we entered. "What have you done to my beautiful wife?" he cried out as he came towards us. This is when the full impact of what I had done sank in, and I realized that I had had no training to deal with this emotional situation, in spite of best intentions. Saddened and stunned, I felt that I had no alternative in the moment, but to leave the husband.

I was given the rest of the afternoon off, but returned to work the next day as though nothing had happened. No one acknowledged the event directly, and there was no conversation about what had happened. Linda had a largely unremarkable recovery and was hospitalized for 10 days. I was told not to initiate any contact with the patient, but I felt committed to being accountable and to establishing a dialogue with the patient. In spite of multiple attempts over the course of her hospital admission, I was summarily prevented from seeing the patient. This was due to the combination of a protective husband, a clinician barrier ("she isn't physically strong enough to have this conversation; we'll take care of it"), and the administration's medical-legal concerns. When the patient was discharged home in good physical condition 10 days later, I felt as though any opportunity for communication had been lost.

See "Reconciliation," Next Page

Barriers Impede Our Response to Adverse Events

"Reconciliation," From Preceding Page

Although the system was telling me that I was better off in not having communicated directly with the patient, I refused to accept that such an abrupt end to a patient care relationship was the correct path to take. I felt very strongly that my integrity was being compromised by the silence, and I felt compelled to find a way to reach out and establish contact. The only available option that I saw was to write a letter to the patient. I resolved that I was going to follow my values of integrity and compassion, regardless of the litigious fallout that might ensue. In the letter I acknowledged the pain and suffering that I had put the patient through, and I apologized for what I had done. I shared the impact that the event had had on me and finished by offering to communicate with the patient at any time should she so desire.

I received no response to my letter from the patient in the 6 months following the event and assumed that there would be no further communication. In May 2000 I was living in Seattle when I received a phone message that the patient had been trying to get in touch with me. Although I was apprehensive, this was the moment that I had tried so hard to achieve. So I went ahead and made the call. The conversation that followed was one of the most uplifting in my life. After clarifying the details about what happened during the event and sharing the emotional impact that this medical trauma had had on both of us, Linda offered me forgiveness for what I had done, explaining that she needed to do this for her own well-being. In an instant it was as though a great weight had been lifted off of my shoulders, and I was free to live my life fully again. We finished by committing to meet in person when we were again in closer geographic proximity.

Patient/Physician:

RvP/LK: We had our first in-person meeting in November 2001 at a local café in Linda's hometown of Mansfield. In addition to further reconciliation and healing at a personal level, Linda shared her frustration and anger about the lack of emotional support that the hospital had offered her in the 2 years since the event, in spite of repeated requests. In looking for national organizations that focused on providing emotional support services around medical events, Linda began to realize that the health care industry's appreciation of the magnitude and the need for these services was largely absent. Realizing that Linda's experience was not an isolated local event and that action had to be taken, Linda and I committed to creating awareness about the challenges and to developing support services for all individuals involved including patients, families, and care providers.

According to the IOM Report "To Err is Human" up to 98,000 deaths occur in United States hospitals due to medical error. If one considers the number of clinicians participating in these patients' care and the immediate family members of these patients, the number of individuals impacted emotionally by these events is greater than 500,000. This number does not include those patients, families, and care providers affected by severe non-fatal adverse events. The IOM report estimates that more than 1 million patients are harmed by medical error each year. The health care industry aspires to emulate the safety culture and processes that the airline industry has successfully implemented to reduce the risk of a passenger fatality to less than 1:10,000,000. Even with this incredible safety achievement, the airline industry recognizes that passenger fatalities will always occur and has an organized and regularly-simulated support response in place for this eventuality. Based on the IOM report, the risk of an error-induced patient fatality is greater than 1:1,000, and yet the vast majority of the health care industry provides no organized support response for affected individuals.

There are a number of barriers that impede our response to adverse events. The Hippocratic Oath that physicians take to "first do no harm," combined with the clinician culture of being emotionally "super human," by necessity precludes the open acknowledgment of adverse events and their emotional toll. A blame-based review process and the fear of litigation when an adverse event occurs further limit disclosure, apology, support, and, as importantly, determining what actually happened during the event. Finally, the emotionally charged nature of these events, which usually involves anger, limits the care provider's desire to engage in conversation with the affected patients and families. The result is an angry health care consumer, traumatized and demoralized care providers, and a health care system that cannot fully implement interventions to correct the care process failure.

Response

Medically Induced Trauma Support Services (MITSS) was incorporated in May 2002 with the mission to "promote healing and restore hope" to all affected by adverse medical events. MITSS offers patient and family support groups, nursing support groups, professional outreach, education, a 24-hour hotline, and a web site (www.mitss.org) to this affected community. The response to MITSS has been extremely positive, and the interest in the support model continues to grow.

The Brigham and Women's Hospital (BWH) has recognized the need to provide an organized response to adverse events for its patients, families, and care providers and has taken active measures to promote full disclosure, apology, and support. In addition to an increased willingness to bring closure to adverse events with open mediation and by referring patients and family members to MITSS via the existing patient and family support services, BWH has created a task force that is developing an education and support program for care providers. The task force will launch a pilot program (SuppORt) in the operating room environment this September, which will serve as a platform for expanded service throughout the rest of the hospital.

As MITSS and BWH continue to expand their leadership roles in the support process around adverse medical events, the challenges remain significant. Education of care providers and visible support by executive hospital leadership are critical if health care's current response to adverse medical events is to be transformed. A patient safety curriculum has been introduced at Harvard Medical School, which includes the MITSS and BWH focus on disclosure, apology, and support around adverse medical events. Education must also be effectively offered to trained clinicians so that the newly implemented support services will be actively utilized. Teaching communication skills around adverse medical events is also critical to an effective and compassionate response. This is likely to be facilitated by open support of senior leadership for such services and through the use of clinicians trained in peer support.

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Ms. Kenney is President of Medically Induced Trauma Support Services, Chestnut Hill, MA.

Ms. Linda Kenney and Dr. van Pelt share their stories wtih participants of the APSF 2005 Workshop on Patient Perspectives After Adverse Events.

Organized Response to Major Anesthesia Accident Will Help Limit Damage

Update of "Adverse Event Protocol" Provides Valuable Plan

by John H. Eichhorn, MD

Precisely because anesthesia care has become so safe in terms of the reduction of major intraoperative anesthesia accidents, very few anesthesia practitioners today have any first-hand experience dealing in real time with a major anesthesia adverse event. While from an overall anesthesia patient safety statistical perspective, this fact is highly desirable, it also functionally represents a new danger. There is absence of experience, training, or even thought about what to do in the extremely unlikely, but yet still possible, event of coming face-to-face with an intraoperative anesthesia catastrophe. This deficit might prevent definitive action that can help the specific patient in a particular incident and patients in general who can benefit by lessons learned from that adverse incident. Application of the principles outlined in what has come to be known as the "Adverse Event Protocol" that was first published in *The Journal of Clinical Anesthesia* in 1993, but is just as relevant today, will overcome the lack of knowledge and experience. This plan of action will help minimize damage to the patient (and also to the involved practitioners) as well as promote understanding and learning that will help prevent recurrence or repetition of the adverse event.

Prior to the mid-late 1980s the prototypical intraoperative anesthesia catastrophe was an unrecognized accidental esophageal intubation during the induction of general anesthesia with muscle relaxation. In such a case, the first indication of trouble often was an expanding stomach and transient tachycardia and hypertension from the sympathetic response to hypoxemia and hypercarbia followed soon by the surgeon making an incision and commenting with distress: "Hey! The blood looks really dark down here!" Ventricular ectopy leading quickly to fibrillation ensued, creating an immediate life-threatening crisis. The necessity was to get help, make the initial diagnosis by recognizing the cause of the problem, replace the endotracheal tube correctly in the trachea, successfully resuscitate the patient, verify that the incident had ended, institute care to minimize hypoxemic damage, and administratively manage the situation, including with investigation and teaching to reduce the probability of it happening again to another patient. Other examples also usually involving some type of failure of ventilation (such as from an unrecognized breathing circuit disconnection) or even a disruption of the oxygen supply are possible, but the point is clear regarding the need to organize the response to such a major event.

By the end of the 1980s the nature of intraoperative anesthesia accidents changed with the creation and universal application of the strategies of intraoperative anesthesia safety monitoring. Specifically the change of behavior and mindset from intermittent to genuinely continuous patient and anesthesia delivery system monitoring coupled with the use of then-new electronic monitors as extensions of the anesthesia provider's senses allowed extremely sensitive real-time monitoring of patient oxygenation and ventilation. This resulted in much earlier warning of the potentially dangerous mishaps (that continue to occur still today) that previously would have evolved to patient injury. The information in the warning, in turn, directed and facilitated diagnosis and correction of the problems well before the onset of injury. As a result, the frequency and severity of intraoperative patient-injury accidents decreased dramatically. Thus, a significant component of the previously traditional training and experience of anesthesia practitioners was functionally eliminated.

While overt unrecognized simple failures of ventilation are much less likely, they can still occur. Also, other, more modern, intraoperative accidents may be more complex and more subtle. Human error theory suggests analogies to other types of major accidents: airliner or train crashes and nuclear plant or electric power grid disasters. These usually involve 2 or more abnormalities or variances in conditions or procedures coincident in time that cause unusual interaction and results, making the operator (or anesthesia practitioner) face an unfamiliar situation. A listing of actual or potential situations is not possible in this setting, but they do happen—very rarely, but they do. Today, applying population statistics, a new practitioner could expect to be involved in a patient-injury accident ***once*** in an average career. This means, by definition, that the practitioner will have no direct experience in managing such a situation. The "Adverse Event Protocol" is specifically intended to fill that gap and arm every anesthesia practitioner with a detailed, carefully thought out plan to respond to a patient-injury intraoperative accident. Laminated copies of the printed protocol were attached to anesthesia machines in some operating rooms (ORs) in the 1990s. Today, a great many OR rooms and virtually all OR suites have immediate Internet access. The original "Adverse Event Protocol" is in the APSF website: **www.apsf.org**, "Clinical Safety Tools" under "Resource Center" at the top of any page on the site. When the urgent overhead page in an OR suite comes, "ANESTHESIA STAT! to OR X," almost always several people respond, usually more than can physically get to the head of the involved patient at one time. One of the helpers later to arrive profitably could either be assigned or take their own initiative to go immediately to an on-line computer and print or even simply read out loud the protocol from the APSF site.

The Basic Plan

Upon recognition that a major adverse anesthesia event is in progress or has occurred:

1. Get help and mobilize according to the protocol–see above for access to the "Adverse Event Protocol" on the Internet.
2. The primary caregiver(s) should continue patient care. Except in the very unusual circumstance that the anesthesia provider becomes ill or disabled or is so shocked by the realization of the accident that s/he cannot function, s/he should devote full attention to direct clinical care rather than to the necessary organizational and administrative considerations.
3. Designate immediately an Incident Supervisor (e.g., a senior practitioner, department leader, or the person running the OR schedule and assignments) who:
   - Assumes overall direction and control of the event.
   - Organizes help and assigns tasks in the OR.
   - Verifies incident has ended and there is no immediate recurrence (e.g. correct intubation and ventilation in the prototype example, continued availability of tank oxygen after a central oxygen supply failure, etc.).
   - Involves consultants and advisors as indicated, including specifically the chief/chair of anesthesiology or appropriate designee, and any others who may help with care or recovery, such as neurologists, cardiologists, etc.
   - Coordinates and facilitates communications (with the surgical team in the OR and then, along with the surgeon, and the primary anesthesia providers if appropriate, with the patient and/or family).
4. Close that OR for that day; do not turn off or unplug anything; access any memory in any monitor or device used (especially the vital signs stored in many OR patient monitors) and print this out or photograph the screen(s) if there is no printing capacity; sequester all involved equipment and supplies (and the trash and needle buckets) and then:
   - Alter nothing (no cleaning, no disassembly, no repair); if it appears likely or even possible that an equipment failure (anesthesia machine ventilator, bubble detector on a rapid infuser, or whatever) contributed to an accident, it may be indicated to conduct an inspection/testing session involving the real-time participation of representatives of the involved practitioners, the equipment

See "Protocol," Next Page

Post Event Protocol is Critically Important

"Protocol," From Preceding Page

manufacturers, the equipment maintenance personnel, facility administration, and involved insurance companies/attorneys.

- Discard nothing; sometimes the solution to a mystery can later be discovered in unexpected tiny details, such as an empty or missing or extra medication vial that suggests an accidental wrong drug administration may have caused the accident.
- Lock away all of the above (this may be difficult in a busy facility; be reasonable; for example, if it is accepted by all involved that there was an unrecognized esophageal intubation involving apparent human error, it would be possible to release the OR and its equipment for use the next day and dispose of the trash).

5. Contact the care facility's administrator and risk manager (possibly also the practitioner's insurance company and attorney if indicated).
6. Arrange immediate comfort and support for patient and/or family. Share as much information as possible. [Discussion of the concept of immediate full disclosure is beyond the scope of this article because of the administrative, risk management, and potential medical-legal implications; however, this concept is currently the subject of widespread attention and discussion.]
7. Designate a Follow-up Supervisor (who may or may not be the same as Incident Supervisor) who will:
   - Verify that the elements of this protocol have been applied.
   - Consider whether to organize a group debriefing (e.g., the day of the event or the following day) involving all those present during the event and function as scribe if indicated (note that there may be medical-legal implications of this and appropriate advice of counsel may be indicated). [Suggested protocols for such a debriefing exist in the literature involving the transportation, infrastructure, and technology industries; relevant medical examples are cited in the protocol's original journal article (reference below).]
   - Maintain ongoing communications with all involved caregivers and patient representatives, coordinating and facilitating as much integration as possible.
   - Pursue the accident investigation in conjunction with involved quality assurance and risk management systems and personnel; eventually prepare a report as indicated, particularly focusing on lessons learned and actions needed to help prevent similar accidents in the future; participate in any peer-review activities conducted regarding the event.
   - File reports as indicated, such as with the FDA and ECRI if it appears that a medical device or medication hazard was involved in the cause of the accident.
8. Document everything:
   - Put strictly objective narrative entries in the medical record and incident report (but these can include background details on the involved thinking, such as, for example, the indication for invasive monitoring based on symptoms and signs of congestive heart failure).
   - (Possibly) make additional detailed (including subjective impressions or value judgments) personal notes for later use—created specifically while sitting with an attorney (personal or from the practitioner's insurance carrier) who keeps them as attorney-client work product.
9. Try to review formal reports submitted by the institution to the authorities (state department of health/licensing body or the National Practitioner Data Bank) both in order to know what they contain and also add your observations or commentary if indicated.
10. Continue involvement after the event when the patient survives:
    - Talk to surgeons and consultants about care; make suggestions as indicated.
    - Be visible, supportive, and not defensive with all involved.
    - Communicate as much as possible (see # 6. above).

Implications

Note that the lack of communication from caregivers and facilities involved in the immediate and longer-term aftermath of major anesthesia accidents was poignantly cited with great distress and even pain from the patient/family survivors' perspective. This was graphically detailed in the previous issue (Eichhorn, JH. Patient perspectives personalize patient safety. *APSF Newsletter* Winter 2005-06;20:61-66) in a report of the first-ever public presentation and discussion by anesthesia accident survivors and is further expanded in a companion article in this issue of the *Newsletter*. Application of the protocol principles will also help address this critical issue.

There are numerous examples of the successful application of the principles outlined in the "Adverse Event Protocol" with beneficial results for all involved, but these are beyond the scope of this particular article. Of course, there are many situations in which the protocol is not indicated, such as an intraoperative patient death that was not anticipated but that clearly was caused by the patient's underlying condition. The application of the protocol is particularly intended for sudden patient-injury accidents in the OR, especially when the anesthesia care may be involved in the causation. Further, a completely unexplained sudden cardiac arrest may well be revealed the next morning at autopsy to have been the result of an unavoidable massive pulmonary embolus, but with that fact being unknown at the time, activation of the protocol during the arrest is certainly appropriate. The learning potential from any application of this protocol is significant, much in the same manner as Emergency Department trauma teams apply evaluation and treatment protocols and later review their efficacy. In all such circumstances (OR, ED, general care floor, etc.) the immediate and long-term intention of the protocol is to prevent and/or mitigate injury to the specific subject patient and all subsequent patients in similar situations.

The Detailed Original Protocol

Reprinted from: Cooper JB, Cullen DJ, Eichhorn JH, Philip JH, Holzman RS. Administrative guidelines for response to an adverse anesthesia event. *J Clin Anesth* 1993; 5:79-84.

Guidelines for Action Following an Adverse Anesthesia Event

Objectives: To limit patient injury from a specific adverse event associated with anesthesia and to ensure that the causes of the events are identified so that a recurrence can be prevented.

Protocol: When a patient has died or has been injured from causes suspected to be related to anesthesia management, the following should occur:

Immediate

1. The primary anesthetist/anesthesiologist should concentrate on continuing patient care. The primary anesthetist/anesthesiologist should notify a physician responsible for supervision of anesthesia activities in the relevant patient care area, e.g., Anesthesia Clinical Director, Anesthesia OR Administrator, Team Leader, as soon as possible (at least before the anesthetist transfers direct responsibility for that patient). The person so contacted will direct the process of immediate prevention of recurrence (if necessary), events documentation and continued investigation or will delegate responsibility to someone other than the primary anesthetist or anesthesiologist. The individual performing these tasks is designated as the "incident supervisor."

Rationale: Information vital to reconstructing events may be accidentally discarded. The highest priority for the primary caregivers must be the care of the patient, so responsibility for administrative and investigate activities

See "Protocol," Next Page

Adverse Events Protocol Originally Published in 1993

"Protocol," From Preceding Page

must be assigned to others. Typically, an anesthesiologist supervising a primary anesthetist/ anesthesiologist should not be the incident supervisor. However, out of normal working hours, a primary or supervising anesthesiologist may choose to act as incident supervisor and may exercise discretion in calling for assistance or advice.

2. Anesthesia equipment or supplies associated with the case, whether thought to be materially involved or not, should be sequestered before subsequent use. Nothing must be altered or discarded. The primary anesthetist/anesthesiologist or incident supervisor shall immediately contact the hospital individual responsible for management of anesthesia equipment and supplies (equipment supervisor). The equipment supervisor or his designee shall supervise the impoundment of involved supplies and equipment (including the anesthesia machine) in consultation with the hospital Risk Manager. A preliminary decision to continue use of urgently needed equipment may be made, following a safety inspection, at the discretion of the incident supervisor in consultation with the hospital Risk Manager.

Rationale: Equipment or supplies involved in the event may be accidentally altered or discarded, preventing determination of cause.

3. The incident supervisor or attending anesthesiologist should contact the hospital Risk Manager immediately following the anesthetic for additional administrative support.

Rationale: Individual caregivers will rarely be experienced in dealing with an adverse occurrence. The Risk Manager can advise on the ways to communicate information to the patient or to the patient's family in a way that is forthright and comforting, but which does not unintentionally alarm, misinform, or render judgment.

4. The primary anesthetist/anesthesiologist and other individuals involved must document relevant information about the incident.

5. The primary anesthetist/anesthesiologist, after discussion with the incident supervisor, must write on the patient's medical record relevant information about what happened and what actions were taken. Do not erase or obscure information on the record. If a correction is necessary, lightly cross out the original; initial and date changes. Additions to and explanations of notations on the record can be made, for example, to explain issues where professional judgment was involved.

6. The primary anesthetist/anesthesiologist must complete and file an incident report as soon as practical.

7. Others individuals involved in the incident should document their observations soon after the event. The documentation should be returned to the hospital Patient Care Assessment Coordinator or other appropriately designated individual. (List designated individual for hospital here.)

8. When writing about the events.
   - State only the facts as you know them.
   - Do not make judgments about causality or responsibility.
   - Do not use judgmental terms or phrases.

9. Give the highest priority to continued involvement in follow-up care of the patient.

1. Consult early and frequently with the surgeon.

2. Immediately call upon other consultants who may help improve long term care or recovery.

Follow-up Investigations

1. The Clinical Directory and/or Department Chairman shall be informed of each adverse event and will designate who shall supervise the event follow-up and investigation beyond the immediate actions. The follow-up supervisor shall:

1. notify the individuals involved of their responsibilities as defined in this document.

2. be responsible for assuring that procedures are followed to the extent necessary, reasonable and possible.

3. maintain communication with those who are providing continuing anesthesia care, providing guidance and advice as needed.

4. ensure that information regarding the adverse event is communicated through the proper channels to the departmental quality assurance program.

2. The need to maintain equipment sequestration shall be determined by the incident follow-up supervisor and the individual responsible for managing anesthesia technology.

1. If it is unlikely the equipment was related to the event, the equipment can be returned to service after routine inspection.

2. If it is possible that the equipment was related to the event, the following procedures should be implemented and supervised by the individual responsible for managing anesthesia technology or his designee:

1. Store the equipment in a secure location. Label it "DO NOT DISTURB."

2. Document its physical condition and notable features as received and record its identification, e.g., serial number.

3. Do not alter or inspect the equipment in any way that could affect further investigation.

4. Conduct a thorough inspection of the equipment in the presence of the primary anesthetist/ anesthesiologist, the insurance carrier, hospital Risk Manager, equipment manufacturers or any of their designees.

3. If an equipment problem or failure is discovered or strongly suspected, the equipment supervisor, after consultation with the hospital Risk Manager, shall consider contacting the Food and Drug Administration (via the Device Experience Network @800-638-6725) and/or the Emergency Care Research Institute (ECRI) if it is believed necessary to warn other users. Alternatively, the manufacturer can communicate that information to the appropriate authorities, which may be required by law depending upon the circumstances.

4. Under the Safe Medical Devices Act, the hospital may be required to report the event to the manufacturer and FDA if a serious injury or death occurred.

5. Continue to verify and document medical care provided to the patient following the event.

Summary of Responsibilities for Adverse Event Protocol

1. Primary Anesthetist/Anesthesiologist: Concentrate on continuing care; notify Anesthesia OR Administrator (or attending first if resident or CRNA); Do NOT discard supplies or apparatus or tamper with equipment; document events in the patient's record; Do NOT alter the record; stay involved with follow-up care; contact consultants as needed; submit a follow-up report; document continuing care in the patient's record.

2. Incident supervisor, e.g., Anesthesia Clinical Director, OR Administrator, Team Leader: Advise primary anesthetist/anesthesiologist and other personnel involved; verify close contact with the surgeon and other consultants; contact the hospital Risk Manager; contact manager for anesthesia equipment or alternate.

3. Department Chairman or Clinical Director: Directly supervise or delegate responsibility for incident investigation.

4. Anesthesia equipment manager or alternate: Assure impounding of equipment, if necessary, and determine appropriate disposition of equipment; if pharmaceuticals or supplies were involved which may create hazard to other patients, contact pharmacy, materials management, nursing or other departments; supervise continuing investigation of equipment or supplied-related issues; contact FDA, ECRI or manufacturer if appropriate.

5. Follow-up Supervisor: Notify the individuals involved of their responsibilities as defined in this documents; be responsible for assuring that procedures are followed to the extent necessary, reasonable and possible; maintain communication with those who are providing continuing anesthesia care, providing guidance and advice as needed; ensure that information regarding the adverse event is communicated through the proper channels to the department quality assurance program.

Conclusion

Accidents will likely continue [very rarely, it is hoped] despite our best efforts to prevent them. Being prepared to organize resources and responses to an accident may limit injury to the patient concerned and prevent injury to subsequent patients. Timely investigation and documentation may be critical to determine cause and to develop a prevention strategy. The opportunity to learn from an accident should not be wasted. [It is anticipated] that implementation of this protocol may help to meet these objectives.

Dr. John Eichhorn, Professor of Anesthesiology at the University of Kentucky, founded the APSF Newsletter *in 1985 and was its editor until 2002. He remains on the Editorial Board and serves as a senior consultant to the APSF Executive Committee.*

Dear SIRS

Channeling Causes Concern

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

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

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

Dear SIRS:

The APSF has received a report of a hypercarbic patient condition during the use of AMSORB® PLUS (Armstrong Medical Limited, Northern Ireland), detected through capnography and confirmed by arterial blood gas monitoring. After inspection, the clinician noted an outward completely white coloration of the absorbent, but a violet coloration of the absorbent channeled through the inner core. After exchange of the absorbent for a fresh container, the hypercarbia reportedly resolved. The clinician further believed that the product literature recommended that the canister be changed when the AMSORB® PLUS indicator completely turns to violet.

APSF recently reported the proceedings of a conference on absorbent desiccation,[1] and there were no such reports of this situation at that conference. Considering the potential significance of this issue, we respectfully ask that Armstrong Medical Limited provide commentary on this report, for the benefit of our readership.

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

1. Olympio, MA. APSF convenes conference on safety concerns of carbon dioxide absorbent desiccation. *APSF Newsletter* 2005;20:25, 27-29.

In Response:

Dear SIRS,

As the manufacturer of AMSORB® PLUS and as a corporate member of APSF, we need to clarify certain performance characteristics and conditions of use of our product. The Instructions for Use (IFU) state that capnography is the primary measurement of exhaustive state, and color is there for indication purposes only. Routine anesthetic monitoring should include $FiCO_2$ and expired CO_2, as we consider this standard practice of anesthetic monitoring. Audio-visual alarms on the monitor, if enabled, will alert the clinician if $FiCO_2$ exceeds 5 mmHg and $ETCO_2$ exceeds 45 mmHg, for example.

We are not aware of any published literature (our own or independently published) that states that the canister be changed when the color has completely changed to violet. This would not make sense, as a completely color-changed canister of AMSORB® PLUS would be desiccated and be incapable of further absorption of CO_2. It appears that since no coloration was observed on the exterior, then that material must have become too moist, preventing a color change or perhaps never had sufficient contact with CO_2 to cause the desiccation necessary for coloration. The reasons for this can be many and we would like an opportunity to look into this.

The IFU states that the canister should be changed when CO_2 breakthrough has reached $FiCO_2$ of 0.5% (or 5 mmHg), which may be associated with color penetrating to two-thirds the depth of the canister. AMSORB® PLUS has a unique color indicator which is intended to give a gradual and permanent color change, unlike soda limes which have a transient and reversible color change which depends on continuous contact with CO_2. With soda lime you will see the color reverting back to white during periods of non-use; this material can become inadvertently desiccated and potentially dangerous when next exposed to anesthetic vapor. This issue is widely published and accepted.

The fact that a clinician experienced color coring/channeling with a completely white exterior is not something that we have come across before, as center coring is normally associated with some level of coloration on the exterior. AMSORB® PLUS color change is gradual and permanent and is intended to be visible throughout the material to a depth of two-thirds the height of the absorber canister before $FiCO_2$ exceeds 0.5% volume or 5 mmHg. What is described by the user may be related to fresh gas flow or particular absorber or user set-up, perhaps from retrograde gas flow during periods of non-use, which is known to cause irregular coloration of AMSORB® PLUS. This would need more investigation and we would appreciate the opportunity to work on this.

If one uses soda lime, the coloration that you see is not related to desiccation. Conversely, there would be no color change to indicate desiccation, and this material could be sufficiently desiccated to degrade the anesthetic whilst simultaneously absorbing CO_2. A common misconception of soda limes is that users believe that they will be alerted to desiccation by failure to absorb CO_2; however, we have done extensive work in our own laboratory, showing that a jumbo canister (2 x 1 kg trays) of completely desiccated soda lime will absorb a clinical loading of CO_2 for at least 1 hour. Published literature would support the contention that this material, once desiccated (inadvertently by fresh gas flow or as part of the normal dehydrating effects of CO_2 absorption) could degrade the anesthetic agent to carbon monoxide, formaldehyde, and other toxic chemicals. Armstrong Medical Limited has offered AMSORB® PLUS as an absorbent that is incapable of degrading the anesthetic agent, in any state of use.

See "Channeling," Next Page

Manufacturer Solicits Input on Coring Cases

"Channeling," From Preceding Page

If any clinician with similar findings is willing to let us look into their channeling claims, then we can arrange for someone to discuss this more fully. In terms of performance problems in other hospitals, we keep in close contact with our distributors worldwide and, in respect to the United States, we are working through some user-specific and machine-specific characteristics in a small number of hospitals. Many of the issues are training related. Given our extensive experience with the characteristics of all commercially available absorbents, we suggest that capnography be used, regardless of which brand of absorbent is chosen.

Please feel free to contact us. Thank you.

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w: www.armstrongmedical.net

Check out the APSF web site at www.apsf.org

APSF Grant Application Deadline is June 19, 2006

Application Guidelines can be found in the previous issue (Winter 2005-2006) or online at www.apsf.org.

Important News

New In-Service Kit Available for Malignant Hyperthermia Response

March 22, 2006

(Sherburne, NY) - Coinciding with its 25th anniversary, the Malignant Hyperthermia Association of the United States (MHAUS), announces the availability of a new, stimulating way to prepare your OR for a malignant hyperthermia (MH) episode. MHAUS (www.mhaus.org) has produced a comprehensive In-service Kit, offering various tools to prepare the OR and PACU staff to recognize, treat, manage, and counsel patients and their families who are subject to this disorder.

MH is an inherited metabolic disorder of muscle, triggered by certain general (gas) anesthetics. If not recognized early enough, death may occur.

"The new In-Service Kit will be an MH recognition tool and corresponding plan of action," says Henry Rosenberg, MD, the President of MHAUS. "It offers medical professionals a thorough review in a convenient package."

The 2006 version includes an entertaining 26-minute video in DVD or VHS format, a mock drill and new information on dantrolene mixing, patient safety, and risk management, and the latest information on the molecular genetic basis for the disorder.

An information booklet with a quiz rounds out the kit, offering 1 CEU for nurses and 1 CME for physicians. The test and Certificate of Completion will soon be accessible at www.mhaus.org.

For more information please visit www.mhaus.org or call MHAUS at 607-674-7901.

About MHAUS

For the past 25 years, MHAUS, a not-for-profit organization, has been fulfilling its mission of eliminating death and disability from MH and similar disorders. The organization provides information and education in multiple formats either free or at a low cost. MHAUS has contributed to the understanding of this complex disorder through extensive data collection and support of scientific research.

Further information on the MH hotline, print, and internet-based education is available at www.mhaus.org or by calling 607-674-7901.

Contact:

Al Rothstein, MHAUS, (866) 636-3342, mhaus@rothsteinmedia.com

The Relevance of Black Box Warnings

by Tricia A. Meyer, PharmD, MS, FASHP

The black box warning placed on droperidol in 2001 reminded clinicians in the perioperative setting of the impact new labeling could have on healthcare facilities, practitioners, patients, and manufacturers. Information on the warning for droperidol was widely disseminated and discussed throughout the anesthesia community. However there are numerous drugs, several of which are of anesthetic interest, which also carry the Food and Drug Administration's (FDA's) black box warning that may be unknown to many clinicians. In addition, many patients undergoing surgical procedures may be currently taking one or more drugs with a black box warning. A recent study in 10 U.S. Health Maintenance Organizations showed that over 40% of ambulatory care patients were receiving at least 1 drug with a boxed warning.[1] The following is a brief review of FDA's process and a website that contains information on drugs that carry black box warnings.

The FDA requires manufacturers of prescription drugs to provide information on their risk in the contraindications, warnings, precautions, and/or adverse reactions sections of the labeling.[2] Serious potential hazards of a drug, as determined by the FDA, may require the addition of a black box warning. There are no written criteria or guidelines as to which events cause the FDA to initiate a boxed warning.[1,2] The Code of Federal Regulations, Title 21, Volume 4, defines and describes the need for a black box warning as:

> Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions"' section of the labeling.[3]

The black box warning indicates the FDA's highest level of risk on available prescription medications.[1,3] The black box appears not only on the package insert but also on promotional material. However, package inserts are lengthy, difficult to read, and are not always readily available to the prescriber. There are over 300 products that carry a black box warning.[4] A 1998 study found 6 criteria that appeared to influence the FDA's decision on black box warning for drug products.[2,5] The research team found that a warning may:

- Identify a drug-associated adverse event that can be prevented through monitoring and intervention
- Identify specific patients for whom the treatment is particularly dangerous
- Advise that the risks of treatment may outweigh the benefits
- Identify a potentially harmful drug interaction or describe critical dosing information
- State that the drug should be administered only by a specially trained health care practitioner or in a special setting
- Caution that the method of drug administration requires exceptional care.[2,5]

Prior to a drug being launched, the FDA reviews and carefully scrutinizes adverse events that occur during the research phase. An adverse event is any undesirable experience a patient has using a medical product. Serious adverse events, which are the ones FDA is interested in, include death, life-threatening situations, initial or prolonged hospitalization, and situations requiring medical intervention to prevent permanent damage, disability, and congenital anomaly. Congenital anomalies include birth defects, miscarriage and stillbirth, or birth with cancer or some other serious disease.[7] If the drug trials report serious and unexpected drug events, then the FDA will make a decision to continue the studies and/or approve the drug.

Many times serious or life-threatening adverse events (reported through adverse drug reports (ADRs) are discovered only after a drug has been on the market for years. These serious side effects surface as the drug is more widely used or is prescribed for off-label uses. The research studies performed prior to approval may not find the adverse effects that occur long after the drug is discontinued or that occur only after years of continuous or chronic use. In 1 study, only half of newly discovered serious ADRs were identified and documented within 7 years after drug approval.[6] These risks may appear to be life-threatening, or they may appear to be less serious. At this point, the FDA and the drug's sponsor will review new, emerging safety information to determine if there is a true safety issue related to the drug and if regulatory or other action is needed. Once an adverse event or product problem is identified, the FDA can take any of the following actions:

- Labeling Changes – Adverse events often prompt the FDA to require the manufacturer to add new information to the product's package insert.
- Boxed Warnings – are reserved for the most serious adverse events. The FDA can require that warnings be placed in a prominent position on the product's packaging to ensure its continued safe use.
- Product Recalls and Withdrawals – are among the most serious actions the FDA can advise a company to take. Recalls involve the firm's removal of a product from the market and may require taking the product off the market permanently.
- Medical and Safety Alerts – are used to provide important safety information about a product to health professionals, trade, and media organizations.

See "Black Box," Page 18

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In memory of Marta O. Corral, MD (Texas Society of Anesthesiologists)

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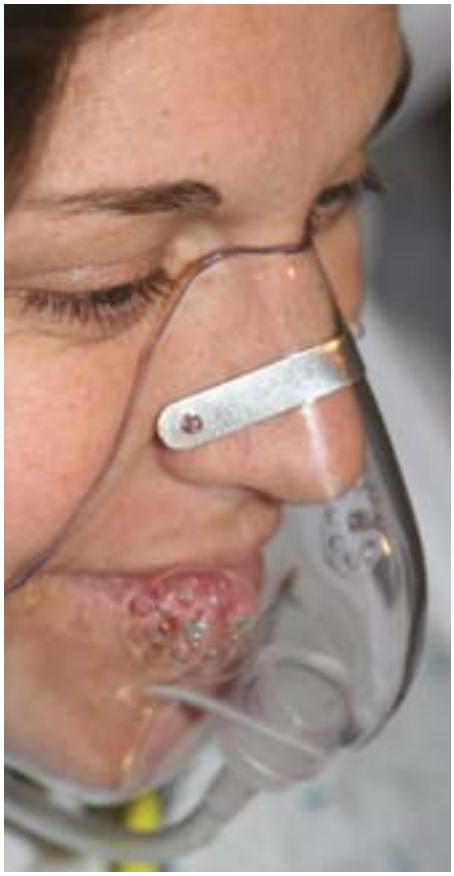
Letter To the Editor:

Supplemental Oxygen is Appropriate



To the Editor:

The recent letter to the editor by Drs. Stemp and Ramsay (Winter 2005-2006, page 80) sought to highlight how the administration of supplemental oxygen might mask the detection of hypoventilation. This occurs because when supplemental oxygen is administered (creating a higher fractional inspired concentration of oxygen) a greater degree of hypoventilation (on the order of 0.5 – 1 L/min) must take place prior to hypoxemia occurring. All good clinicians know, however, that oxygenation and ventilation should be monitored separately and by different means. Relying on, or even using, hypoxemia as detected by pulse oximetry to monitor and detect hypoventilation reminds me of the days when we used the EKG (or even a precordial stethoscope!) to detect hypoxemia by the onset of bradycardia. Anyone who remembers those days has an added appreciation of the value of pulse oximetry and the reduced stress levels it creates for patients and anesthesia providers alike. The fact that supplemental oxygen delays the onset of hypoxemia even if patients are hypoventilating should be taught and appreciated by all clinicians administering sedation or anesthesia. However, I disagree with the interpretation of this fact by Drs. Stemp and Ramsey. Indeed this is why supplemental oxygen should be given to most if not all patients undergoing sedation or anesthesia. Administering supplemental oxygen will lower the incidence and/or severity of hypoxemia even in the presence of hypoventilation, which is expected and common in patients undergoing sedation. Since it is hypoxemia and not hypercarbia that most often precipitates or is associated with severe negative outcomes in sedation settings, avoiding hypoxemia is imperative. I believe that allowing hypoxemia to occur or advocating that steps taken to reduce hypoxemia may be counterproductive, as Drs. Stemp and Ramsay argue, is misguided. Their contention at best recognizes that, all too often, some clinicians do resort to using pulse oximetry as the sole monitor of breathing. This practice should not, however, be condoned. Clinicians should always monitor minute ventilation by one or more means independently of oxygenation, and never rely on pulse oximetry as the monitor of ventilatory status. Various means can be used to assess ventilation independent of oxygenation and include assessments of the patient's responsiveness, respiratory rate, rate and pattern of abdominal and thoracic excursion, the need for and effect of a gentle jaw thrust, and capnography, which is inexpensive and greatly underutilized in many sedation settings.

Peter Bailey, MD
Rochester, NY

Clinicians Should Understand Warnings

"Black Box," From Page 16

Most drugs, prescriptions and non-prescription, have risks associated with their use. Prescribers must consider these risks and the drug's benefits when determining drug therapy for the patient. The boxed warning of a drug has been considered by some courts as adequate warning to prescribers of a drug's risk, and therefore protects the manufacturer from product liability.[2] Understanding black box warnings for drugs may help the clinician evaluate the optimal drug regimen for patients. The Drug Information Center under the direction of Joyce Generali MS, RPh, at Kansas University Medical Center has a helpful and easy to use web page to provide black box warning information: www.formularyproductions.com/master/showpage.php?dir=blackbox&whichpage=238.

The drugs are categorized by a comprehensive list, alpha index, and by therapeutic class. It is very difficult for clinicians to keep informed of the many black box warnings. This website can help inform practitioners on current and important drug safety information.

Dr. Meyer is Director of the Department of Pharmacy and an Assistant Professor in the Department of Anesthesiology at Texas A&M College of Medicine, Scott and White Healthcare System, Temple, TX. She is also a member of the APSF Committee on Education and Training.

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Letter to the Editor:

Radiation Prevents Presence in Room

The issue of an anesthesiologist's physical presence, or lack of, in the radiology suite raised by Timothy W. Martin is addressed by the ASA's *"Standard for Basic Monitoring"*[1] both in general and in particular. In the introductory paragraph, the Standard states that, "In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical," and "Brief interruptions of continual monitoring may be unavoidable." The Standard then goes on to describe the actions that the anesthesiologist should take under these circumstances. This statement should in general adequately cover the situation of brief absences during radiation treatment.

Under STANDARD I (Presence in the room)[2] in the section described as OBJECTIVE, the second sentence specifically addresses radiation therapy and what actions should be taken if the anesthesia personnel have to leave the room because of the radiation hazard to personnel. This covers the situation in radiation therapy in particular.

However, several other issues are also raised. The first is that state law, if it forbids the presence of any other person in the room during radiation therapy as it does in Maine,[3] will pre-empt any standard from a professional organization. A standard only represents an opinion, albeit one with the force of a national organization, and thus is a lower ranking document. If you disagree with state law, you can work to change it, but until that time you must work with the tools that are available to make the procedure as safe as possible within those constraints. If you feel that the situation is so unsafe that therapy should not be administered, it should be because of other correctable issues, not just because of a standard that is in conflict with state law.

These 2 elements show that the ASA Standards for Basic Monitoring do not need revision as they already adequately cover the situation.

Bernard C. DeLeo, MD,[4] raises a similar issue concerning the presence of anesthesia personnel present in the scanner during MRIs. He feels that anesthesia personnel should be actually in the magnet room, though an informal survey at a refresher course suggests that 50% of the attendees feel this is not required.[4]

Timothy Martin's letter raises the question, is the important issue actually being "in the room" or being able "to see" the patient, even if it is through shielded glass or via a video camera? Ironically, when a pediatric patient is in the scanner tube, all bundled up, you cannot see anything of the patient except the anesthesia reservoir bag (if the patient has a "contained" airway and is breathing spontaneously) even if you are in the in the magnet. You are totally dependent on your monitoring for any quantitative information on what is happening.

Perhaps the requirement for a physical presence (apart from the need to be there to actually administer the anesthesia) arose in part because in the early days of anesthesia, monitoring was pretty much limited to what you could hear, sees, feel, or smell. With traditional monitors and other newer modalities of monitoring, all amenable to signal processing, physical proximity to the patient may be less of an issue (assuming the ability to intervene at short notice) provided that you can still "see." Mark Warner, MD, during the Rovenstine Lecture at the 2005 ASA in Atlanta challenged the audience to look for new ways to deliver anesthesia care. Maine Medical Center (Portland, Maine) has just introduced E-Care whereby an intensive care physician is available for consultation for patients at a remote location.

Could the same scenario potentially happen for anesthesia, with the clinician being present electronically rather than physically?

Richard M. Flowerdew, MB
Portland, ME

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APSF Announces a New Patient Safety Initiative:

Safety During Patient-Controlled Analgesia (PCA)

The October 13, 2006, APSF Board of Directors Workshop will address issues of drug-induced depression of ventilation during PCA and potential opportunities to recognize at-risk patients via clinical evaluation and monitoring of oxygenation and ventilation.

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